EXHIBIT B

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SUPERIOR COURT OF NEW JERSEY

LAW DIVISION - ATLANTIC COUNTY

CIVIL ACTION

:CASE NO. :291 CT

IN RE:

PELVIC MESH/GYNECARE LITIGATION :MASTER CASE :6341-10

CONFIDENTIAL

SUBJECT TO STIPULATION AND ORDER OF CONFIDENTIALITY

November 13, 2015

Continued videotape realtime deposition of MARTIN WEISBERG, M.D., was taken pursuant to notice and held at the law offices of RIKER DANZIG HYLAND PERRETTI LLP, Headquarters Plaza, One Speedwell Avenue, Morristown, New Jersey, beginning at 9:42 a.m. on the above date, before Kimberly A. Cahill, a Federally Approved Registered Merit Reporter and Notary Public for the State of New Jersey.

GOLKOW TECHNOLOGIES, INC. 877.370.3377 ph 917.591.5672 fax deps@golkow.com

Golkow Technologies, Inc. - 1.877.370.DEPS

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1	Transcript of the continued	1	BUTLER SNOW LLP BY: WILLIAM M. GAGE, ESQUIRE
2	deposition of MARTIN WEISBERG, M.D., called for	2	1020 Highland Colony Parkway, Suite 1400
3	Videotape Examination in the above-captioned matter,	3	Ridgeland, Mississippi 39157 (601) 948-5711
4	said deposition taken pursuant to Superior Court		william.gage@butlersnow.com
5	Rules of Practice and Procedure by and before	4	Representing the Johnson & Johnson and Ethicon Defendants
7	KIMBERLY A. CAHILL, a Federally Approved Registered Merit Reporter, Certified Court Reporter, and Notary	5	
8	Public for the State of New Jersey, at the offices	6	, , , , , , , , , , , , , , , , , , , ,
9	of RIKER DANZIG SCHERER HYLAND PERRETTI LLP,	7	BY: RICHARD T. BERNARDO, ESQUIRE (via telephone)
10	Headquarters Plaza, One Speedwell Avenue,	8	4 Times Square New York, New York 10036
11	Morristown, New Jersey, commencing at 9:42 a.m.	ľ	(212) 735-3453
12	5.55.55.55.55.55.55.55.55.55.55.55.55.5	9	
13		10	Representing the Johnson & Johnson and Ethicon Defendants
14		11	
15		12	VIDEOTAPE TECHNICIAN:
16			Dale Swindell
17		13	
18		15	5
19		16 17	
20		18	
21		19 20	
22		21	
23		22	
24		23	
25		25	5
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1 2	APPEARANCES:	1 2	
	HEARD ROBINS CLOUD LLP	3	
	BY: ALEX BARLOW, ESQUIRE 2000 West Loop South	4 5	Testimony of: MARTIN WEISBERG, M.D.
4	22nd Floor Houston, Texas 77027	6	By Mr. Barlow 304
5	(713) 650-1200 barlow@heardrobins.com	7	By Mr. Freese 381 By Mr. Gage 457
6	Representing the MDL Plaintiffs	8	By Mr. Freese 527 By Mr. Barlow 581
'	FREESE & GOSS, PLLC		By Mr. Gage 603
	BY: RICHARD A. FREESE, ESQUIRE Regions Harbert Plaza 1901	9 10	
9	6th Avenue North, Suite 3120 Birmingham, Alabama 35203	11	EXHIBITS
10	(205) 871-4144 rich@freeseandgoss.com	12 13	
	Representing the Texas Plaintiffs	14	NO. DESCRIPTION PAGE
12	KLINE & SPECTER, P.C.	15	5 D-1 Ethicon Response to Section 459
13	BY: CATHERINE A. FOLEY, ESQUIRE (via telephone)	16	39 Request and Attachments, ETH.MESH.22631022 through
14	The Nineteenth Floor 1525 Locust Street		ETH.MESH.22632029
	Philadelphia, Pennsylvania 19102	17	D-2 7/29/14 CAPA-003474, 476
	(215) 772-1000 Catherine.Foley@KlineSpecter.com	18	ETH.MESH.22625140 through
17	Representing the Plaintiffs	19	
18	RIKER DANZIG SCHERER HYLAND PERRETTI LLP BY: MAHA M. KABBASH, ESQUIRE	20	D-3 2008 TVT Brochure, 481 ETH.MESH.08003279 through
19	Headquarters Plaza One Speedwell Avenue		ETH.MESH.08003294
20	Morristown, New Jersey 07962-1981	21	D-4 2012 TVT Brochure, 483
21	(973) 538-0800 mkabbash@riker.com	22	ETH.MESH.09744858 through
22	Representing the Johnson & Johnson and Ethicon Defendants	23	
23 24		24	D-5 1/15 E-Mail Chain, 488 ETH.MESH.22631008
25		25	

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1 Kluesner Attaching Add-To-File Submission, etc., 2 Beginning with ETH.MESH.22617620		1 2 3	DEPOSITION SUPPORT INDEX
D-7 E-Mail Chain and Attachments, 496 4 Beginning with ETH.MESH.22865906		4 5	Direction to Witness Not to Answer
5 D-8 6/4/15 E-Mail from Andrews to 500 6 Kluesner, ETH.MESH.22634691 and ETH.MESH.22634692		6 7 8	Page Line Page Line Request for Production of Documents
D-9 Six-Page Document Labeled 503 "Chronology" 9 D-10 6/5/15 E-Mails, with First 506		9	Page Line Page Line Page Line
One from Andrews to Kluesner, ETH.MESH.22865922 11 P-1656 9/24/15-Present TVT Abbrevo 303 IFU, HMESH_ETH_11049264 12 through HMESH_ETH 11049274		11	Stipulations
12 through HMESH_ETH_11049274 13 P-1657 9/10/10-11/27/14 TVT Abbrevo 333 1FU, ETH.MESH.02341203 14 through ETH.MESH.02341213 15 P-1658 11/6/15 Updated IFU Index and 335		13	Page Line Page Line Page Line
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1 ETH.MESH.02618018 2 P-1664 8/5/13-10/17/13 TVT Exact 357 IFU, ETH.MESH.10670138 3 through ETH.MESH.10670144 4 P-1665 E-Mail Chain, 382		1 2 3 4	Reserved for Confidential Designation Index as Pursuant to the Protective Order
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ETH.MESH.176324274 and 9 ETH.MESH.176324275 10 P-1668 5/8/14 E-Mail Chain, 425		10 11	
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20 21 22		21 22	
23 24 25		23 24 25	

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	Page 302		Page 304
1	Reserved for Confidential Designation Index as	1	BY MR. BARLOW:
2	Pursuant to the Protective Order	2	Q. Good morning, Dr. Weisberg.
3		3	A. Hello.
4		4	Q. I'm Alex Barlow. We met yesterday.
5		5	A. Yes.
6		6	Q. And I'm going to be continuing with
7		7	your questioning today.
8		8	I'm going to hand you a document that
9		9	I've marked P-1656, and I will represent to you that
10		10	that is the TVT Abbrevo IFU that Ethicon has
11		11	produced in this case and represented to us was in
12		12	use from September 24, 2015 to the present day.
13		13	Take a look at that and confirm it for me, please.
14		14	And here, Maha I'm sorry, Maha.
15		15	MR. GAGE: It's probably better to
16		16	hand them to her because she can kind of look, check
17		17	in on it and make sure that
18		18	MR. BARLOW: Make sure I'm not
19		19	MR. GAGE: Yep.
20		20	MR. BARLOW: getting the wrong
21		21	one.
22		22	
23		23	MR. GAGE: She's going to go get her chart, but you go ahead and keep going with him. If
24		24	there's a problem, she'll let us know when she comes
25		25	back.
25	Page 303	23	Page 305
1	_	1	
1 2	THE VIDEO TECHNICIAN: We're now on	2	(Pause.) THE WITNESS: Yes.
3	the record. My name is Dale Swindell. I am a	3	BY MR. BARLOW:
4	videographer for Golkow Technologies. Today's date	4	
5	is November 13th, 2015 and the time is 9:42 a.m.	5	Q. And, Doctor, I'm going to ask you we're going to go through. I'm going to ask you to
)	
6 7	This video deposition is being held	6	compare that to Exhibit 1640, which is the list of
7	in Morristown, New Jersey in the matter of In Re:	6 7	compare that to Exhibit 1640, which is the list of adverse reactions for TVT.
7 8	in Morristown, New Jersey in the matter of In Re: Pelvic Mesh/Gynecare (Atlantic). The deponent is	6 7 8	compare that to Exhibit 1640, which is the list of adverse reactions for TVT. A. Okay.
7 8 9	in Morristown, New Jersey in the matter of In Re: Pelvic Mesh/Gynecare (Atlantic). The deponent is Martin Weisberg, M.D. Counsel will be noted on the	6 7 8 9	compare that to Exhibit 1640, which is the list of adverse reactions for TVT. A. Okay. Q. First, let me ask you about 1640.
7 8 9 10	in Morristown, New Jersey in the matter of In Re: Pelvic Mesh/Gynecare (Atlantic). The deponent is Martin Weisberg, M.D. Counsel will be noted on the stenographic record.	6 7 8 9 10	compare that to Exhibit 1640, which is the list of adverse reactions for TVT. A. Okay. Q. First, let me ask you about 1640. All of the adverse reactions listed on Exhibit 1640
7 8 9 10 11	in Morristown, New Jersey in the matter of In Re: Pelvic Mesh/Gynecare (Atlantic). The deponent is Martin Weisberg, M.D. Counsel will be noted on the stenographic record. The court reporter is Kimberly Cahill	6 7 8 9 10	compare that to Exhibit 1640, which is the list of adverse reactions for TVT. A. Okay. Q. First, let me ask you about 1640. All of the adverse reactions listed on Exhibit 1640 are adverse reactions that can occur with the TVT
7 8 9 10 11 12	in Morristown, New Jersey in the matter of In Re: Pelvic Mesh/Gynecare (Atlantic). The deponent is Martin Weisberg, M.D. Counsel will be noted on the stenographic record.	6 7 8 9 10 11 12	compare that to Exhibit 1640, which is the list of adverse reactions for TVT. A. Okay. Q. First, let me ask you about 1640. All of the adverse reactions listed on Exhibit 1640 are adverse reactions that can occur with the TVT Abbrevo; correct?
7 8 9 10 11 12 13	in Morristown, New Jersey in the matter of In Re: Pelvic Mesh/Gynecare (Atlantic). The deponent is Martin Weisberg, M.D. Counsel will be noted on the stenographic record. The court reporter is Kimberly Cahill and will now swear in the witness.	6 7 8 9 10 11 12 13	compare that to Exhibit 1640, which is the list of adverse reactions for TVT. A. Okay. Q. First, let me ask you about 1640. All of the adverse reactions listed on Exhibit 1640 are adverse reactions that can occur with the TVT Abbrevo; correct? A. Yes.
7 8 9 10 11 12 13	in Morristown, New Jersey in the matter of In Re: Pelvic Mesh/Gynecare (Atlantic). The deponent is Martin Weisberg, M.D. Counsel will be noted on the stenographic record. The court reporter is Kimberly Cahill and will now swear in the witness. MARTIN WEISBERG, M.D., after having	6 7 8 9 10 11 12 13	compare that to Exhibit 1640, which is the list of adverse reactions for TVT. A. Okay. Q. First, let me ask you about 1640. All of the adverse reactions listed on Exhibit 1640 are adverse reactions that can occur with the TVT Abbrevo; correct? A. Yes. Q. And all of the reactions, the adverse
7 8 9 10 11 12 13 14	in Morristown, New Jersey in the matter of In Re: Pelvic Mesh/Gynecare (Atlantic). The deponent is Martin Weisberg, M.D. Counsel will be noted on the stenographic record. The court reporter is Kimberly Cahill and will now swear in the witness. MARTIN WEISBERG, M.D., after having been duly sworn, was examined and	6 7 8 9 10 11 12 13 14	compare that to Exhibit 1640, which is the list of adverse reactions for TVT. A. Okay. Q. First, let me ask you about 1640. All of the adverse reactions listed on Exhibit 1640 are adverse reactions that can occur with the TVT Abbrevo; correct? A. Yes. Q. And all of the reactions, the adverse reactions, listed on 1640, Exhibit 1640, are adverse
7 8 9 10 11 12 13 14 15	in Morristown, New Jersey in the matter of In Re: Pelvic Mesh/Gynecare (Atlantic). The deponent is Martin Weisberg, M.D. Counsel will be noted on the stenographic record. The court reporter is Kimberly Cahill and will now swear in the witness. MARTIN WEISBERG, M.D., after having	6 7 8 9 10 11 12 13 14 15	compare that to Exhibit 1640, which is the list of adverse reactions for TVT. A. Okay. Q. First, let me ask you about 1640. All of the adverse reactions listed on Exhibit 1640 are adverse reactions that can occur with the TVT Abbrevo; correct? A. Yes. Q. And all of the reactions, the adverse reactions, listed on 1640, Exhibit 1640, are adverse reactions that were known to be something that could
7 8 9 10 11 12 13 14 15 16	in Morristown, New Jersey in the matter of In Re: Pelvic Mesh/Gynecare (Atlantic). The deponent is Martin Weisberg, M.D. Counsel will be noted on the stenographic record. The court reporter is Kimberly Cahill and will now swear in the witness. MARTIN WEISBERG, M.D., after having been duly sworn, was examined and testified as follows:	6 7 8 9 10 11 12 13 14 15 16	compare that to Exhibit 1640, which is the list of adverse reactions for TVT. A. Okay. Q. First, let me ask you about 1640. All of the adverse reactions listed on Exhibit 1640 are adverse reactions that can occur with the TVT Abbrevo; correct? A. Yes. Q. And all of the reactions, the adverse reactions, listed on 1640, Exhibit 1640, are adverse reactions that were known to be something that could occur with regard to the TVT family of products when
7 8 9 10 11 12 13 14 15 16 17	in Morristown, New Jersey in the matter of In Re: Pelvic Mesh/Gynecare (Atlantic). The deponent is Martin Weisberg, M.D. Counsel will be noted on the stenographic record. The court reporter is Kimberly Cahill and will now swear in the witness. MARTIN WEISBERG, M.D., after having been duly sworn, was examined and testified as follows: (Deposition Exhibit No. P-1656,	6 7 8 9 10 11 12 13 14 15 16 17	compare that to Exhibit 1640, which is the list of adverse reactions for TVT. A. Okay. Q. First, let me ask you about 1640. All of the adverse reactions listed on Exhibit 1640 are adverse reactions that can occur with the TVT Abbrevo; correct? A. Yes. Q. And all of the reactions, the adverse reactions, listed on 1640, Exhibit 1640, are adverse reactions that were known to be something that could occur with regard to the TVT family of products when at the initial launch of the original TVT;
7 8 9 10 11 12 13 14 15 16 17 18	in Morristown, New Jersey in the matter of In Re: Pelvic Mesh/Gynecare (Atlantic). The deponent is Martin Weisberg, M.D. Counsel will be noted on the stenographic record. The court reporter is Kimberly Cahill and will now swear in the witness. MARTIN WEISBERG, M.D., after having been duly sworn, was examined and testified as follows: (Deposition Exhibit No. P-1656, 9/24/15-Present TVT Abbrevo IFU,	6 7 8 9 10 11 12 13 14 15 16 17 18	compare that to Exhibit 1640, which is the list of adverse reactions for TVT. A. Okay. Q. First, let me ask you about 1640. All of the adverse reactions listed on Exhibit 1640 are adverse reactions that can occur with the TVT Abbrevo; correct? A. Yes. Q. And all of the reactions, the adverse reactions, listed on 1640, Exhibit 1640, are adverse reactions that were known to be something that could occur with regard to the TVT family of products when at the initial launch of the original TVT; correct?
7 8 9 10 11 12 13 14 15 16 17 18 19 20	in Morristown, New Jersey in the matter of In Re: Pelvic Mesh/Gynecare (Atlantic). The deponent is Martin Weisberg, M.D. Counsel will be noted on the stenographic record. The court reporter is Kimberly Cahill and will now swear in the witness. MARTIN WEISBERG, M.D., after having been duly sworn, was examined and testified as follows: (Deposition Exhibit No. P-1656, 9/24/15-Present TVT Abbrevo IFU, HMESH_ETH_11049264 through	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	compare that to Exhibit 1640, which is the list of adverse reactions for TVT. A. Okay. Q. First, let me ask you about 1640. All of the adverse reactions listed on Exhibit 1640 are adverse reactions that can occur with the TVT Abbrevo; correct? A. Yes. Q. And all of the reactions, the adverse reactions, listed on 1640, Exhibit 1640, are adverse reactions that were known to be something that could occur with regard to the TVT family of products when at the initial launch of the original TVT; correct? A. I don't know that there was any
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	in Morristown, New Jersey in the matter of In Re: Pelvic Mesh/Gynecare (Atlantic). The deponent is Martin Weisberg, M.D. Counsel will be noted on the stenographic record. The court reporter is Kimberly Cahill and will now swear in the witness. ARTIN WEISBERG, M.D., after having been duly sworn, was examined and testified as follows: (Deposition Exhibit No. P-1656, 9/24/15-Present TVT Abbrevo IFU, HMESH_ETH_11049264 through HMESH_ETH_11049274, was marked for	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	compare that to Exhibit 1640, which is the list of adverse reactions for TVT. A. Okay. Q. First, let me ask you about 1640. All of the adverse reactions listed on Exhibit 1640 are adverse reactions that can occur with the TVT Abbrevo; correct? A. Yes. Q. And all of the reactions, the adverse reactions, listed on 1640, Exhibit 1640, are adverse reactions that were known to be something that could occur with regard to the TVT family of products when at the initial launch of the original TVT; correct? A. I don't know that there was any documentation of excessive contraction at that time.
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	in Morristown, New Jersey in the matter of In Re: Pelvic Mesh/Gynecare (Atlantic). The deponent is Martin Weisberg, M.D. Counsel will be noted on the stenographic record. The court reporter is Kimberly Cahill and will now swear in the witness. MARTIN WEISBERG, M.D., after having been duly sworn, was examined and testified as follows: (Deposition Exhibit No. P-1656, 9/24/15-Present TVT Abbrevo IFU, HMESH_ETH_11049264 through	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	compare that to Exhibit 1640, which is the list of adverse reactions for TVT. A. Okay. Q. First, let me ask you about 1640. All of the adverse reactions listed on Exhibit 1640 are adverse reactions that can occur with the TVT Abbrevo; correct? A. Yes. Q. And all of the reactions, the adverse reactions, listed on 1640, Exhibit 1640, are adverse reactions that were known to be something that could occur with regard to the TVT family of products when at the initial launch of the original TVT; correct? A. I don't know that there was any documentation of excessive contraction at that time. It was hypothetical.
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	in Morristown, New Jersey in the matter of In Re: Pelvic Mesh/Gynecare (Atlantic). The deponent is Martin Weisberg, M.D. Counsel will be noted on the stenographic record. The court reporter is Kimberly Cahill and will now swear in the witness. MARTIN WEISBERG, M.D., after having been duly sworn, was examined and testified as follows: (Deposition Exhibit No. P-1656, 9/24/15-Present TVT Abbrevo IFU, HMESH_ETH_11049264 through HMESH_ETH_11049274, was marked for identification.)	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	compare that to Exhibit 1640, which is the list of adverse reactions for TVT. A. Okay. Q. First, let me ask you about 1640. All of the adverse reactions listed on Exhibit 1640 are adverse reactions that can occur with the TVT Abbrevo; correct? A. Yes. Q. And all of the reactions, the adverse reactions, listed on 1640, Exhibit 1640, are adverse reactions that were known to be something that could occur with regard to the TVT family of products when at the initial launch of the original TVT; correct? A. I don't know that there was any documentation of excessive contraction at that time. It was hypothetical. Q. It was it was known to be a
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	in Morristown, New Jersey in the matter of In Re: Pelvic Mesh/Gynecare (Atlantic). The deponent is Martin Weisberg, M.D. Counsel will be noted on the stenographic record. The court reporter is Kimberly Cahill and will now swear in the witness. ARTIN WEISBERG, M.D., after having been duly sworn, was examined and testified as follows: (Deposition Exhibit No. P-1656, 9/24/15-Present TVT Abbrevo IFU, HMESH_ETH_11049264 through HMESH_ETH_11049274, was marked for	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	compare that to Exhibit 1640, which is the list of adverse reactions for TVT. A. Okay. Q. First, let me ask you about 1640. All of the adverse reactions listed on Exhibit 1640 are adverse reactions that can occur with the TVT Abbrevo; correct? A. Yes. Q. And all of the reactions, the adverse reactions, listed on 1640, Exhibit 1640, are adverse reactions that were known to be something that could occur with regard to the TVT family of products when at the initial launch of the original TVT; correct? A. I don't know that there was any documentation of excessive contraction at that time. It was hypothetical.

4 (Pages 302 to 305)

	Page 306		Page 308
1	A. I think it was hypothesized.	1	adverse reactions listed on 1640; correct?
2	Q. When were the first reports of	2	A. If feasible means could it be done
3	excessive contraction that you're aware of?	3	could it have been done, yes.
4	A. For TVT?	4	Q. And it would have been feasible at
5	Q. Uh-hum.	5	the time of the launch of the TVT Abbrevo to warn of
6	A. I don't know that I can recall any	6	all of the adverse reactions listed on 1640;
7	documentation of excessive contraction. I just	7	correct?
8	don't know.	8	A. Yes.
9	Q. Okay.	9	Q. And it would have been reasonable to
10	It was a risk that was considered as	10	warn of all of the adverse reactions listed on 1640
11	a reasonable possibility at the launch of the	11	at the time of the launch of the Abbrevo; correct?
12	original TVT that there could be excessive	12	A. I'm hesitating because I don't know
13	contraction; correct?	13	that there was enough evidence to include excessive
14	A. Well, it was only hypothesized	14	contraction; and then if if that evidence did not
15	because the device was new.	15	exist, then it might not have been reasonable.
16	Q. What preclinical testing or prelaunch	16	Q. You don't know one way or the other
17	clinical testing did you do to exclude the	17	whether or not there was enough evidence of
18	possibility of excessive contraction before the	18	excessive contraction at the time of the launch of
19	launch of the original TVT?	19	the Abbrevo as to whether or not it would have been
20	MR. GAGE: Objection; beyond the	20	reasonable to include that?
21	scope.	21	A. That's right.
22	THE WITNESS: I don't have that	22	Q. You included it, obviously, after the
23	information in my head. I would need to look it up.	23	Health Canada inquiry; correct?
24	BY MR. BARLOW:	24	MR. GAGE: Object to form.
25	Q. As you sit here today, can you	25	THE WITNESS: We notified Health
	Page 307		Page 309
1	identify any clinical testing that was done on the	1	~
_			Canada that we would include it lives
2	original TVT before launch to inquire about whether		Canada that we would include it, yes.
2	original TVT before launch to inquire about whether	2	BY MR. BARLOW:
3	or not excessive contraction was something more than	2	BY MR. BARLOW: Q. You notified Health Canada that you
3 4	or not excessive contraction was something more than a hypothesized risk?	2 3 4	BY MR. BARLOW: Q. You notified Health Canada that you would include it, but it did not actually appear in
3 4 5	or not excessive contraction was something more than a hypothesized risk? MR. GAGE: Objection; beyond the	2 3 4 5	BY MR. BARLOW: Q. You notified Health Canada that you would include it, but it did not actually appear in the TVT Abbrevo.
3 4 5 6	or not excessive contraction was something more than a hypothesized risk? MR. GAGE: Objection; beyond the scope.	2 3 4 5 6	BY MR. BARLOW: Q. You notified Health Canada that you would include it, but it did not actually appear in the TVT Abbrevo. A. That's right.
3 4 5	or not excessive contraction was something more than a hypothesized risk? MR. GAGE: Objection; beyond the scope. Go ahead.	2 3 4 5 6 7	BY MR. BARLOW: Q. You notified Health Canada that you would include it, but it did not actually appear in the TVT Abbrevo. A. That's right. Q. IFU.
3 4 5 6 7 8	or not excessive contraction was something more than a hypothesized risk? MR. GAGE: Objection; beyond the scope. Go ahead. THE WITNESS: I don't recall any.	2 3 4 5 6	BY MR. BARLOW: Q. You notified Health Canada that you would include it, but it did not actually appear in the TVT Abbrevo. A. That's right. Q. IFU. A. That's correct.
3 4 5 6 7 8 9	or not excessive contraction was something more than a hypothesized risk? MR. GAGE: Objection; beyond the scope. Go ahead. THE WITNESS: I don't recall any. BY MR. BARLOW:	2 3 4 5 6 7 8 9	BY MR. BARLOW: Q. You notified Health Canada that you would include it, but it did not actually appear in the TVT Abbrevo. A. That's right. Q. IFU. A. That's correct. Q. With the exception of the excessive
3 4 5 6 7 8 9	or not excessive contraction was something more than a hypothesized risk? MR. GAGE: Objection; beyond the scope. Go ahead. THE WITNESS: I don't recall any. BY MR. BARLOW: Q. Doctor, with regard to the other	2 3 4 5 6 7 8 9	BY MR. BARLOW: Q. You notified Health Canada that you would include it, but it did not actually appear in the TVT Abbrevo. A. That's right. Q. IFU. A. That's correct. Q. With the exception of the excessive contraction, all of the adverse reactions listed on
3 4 5 6 7 8 9 10	or not excessive contraction was something more than a hypothesized risk? MR. GAGE: Objection; beyond the scope. Go ahead. THE WITNESS: I don't recall any. BY MR. BARLOW: Q. Doctor, with regard to the other adverse reactions listed on 1640, were all those	2 3 4 5 6 7 8 9 10	BY MR. BARLOW: Q. You notified Health Canada that you would include it, but it did not actually appear in the TVT Abbrevo. A. That's right. Q. IFU. A. That's correct. Q. With the exception of the excessive contraction, all of the adverse reactions listed on 1640 would have been reasonable to warn of at the
3 4 5 6 7 8 9 10 11 12	or not excessive contraction was something more than a hypothesized risk? MR. GAGE: Objection; beyond the scope. Go ahead. THE WITNESS: I don't recall any. BY MR. BARLOW: Q. Doctor, with regard to the other adverse reactions listed on 1640, were all those adverse reactions known by Ethicon to be risk	2 3 4 5 6 7 8 9 10 11	BY MR. BARLOW: Q. You notified Health Canada that you would include it, but it did not actually appear in the TVT Abbrevo. A. That's right. Q. IFU. A. That's correct. Q. With the exception of the excessive contraction, all of the adverse reactions listed on 1640 would have been reasonable to warn of at the time of the launch of the Abbrevo; correct?
3 4 5 6 7 8 9 10 11 12 13	or not excessive contraction was something more than a hypothesized risk? MR. GAGE: Objection; beyond the scope. Go ahead. THE WITNESS: I don't recall any. BY MR. BARLOW: Q. Doctor, with regard to the other adverse reactions listed on 1640, were all those adverse reactions known by Ethicon to be risk adverse reactions that could occur with the TVT	2 3 4 5 6 7 8 9 10 11 12 13	BY MR. BARLOW: Q. You notified Health Canada that you would include it, but it did not actually appear in the TVT Abbrevo. A. That's right. Q. IFU. A. That's correct. Q. With the exception of the excessive contraction, all of the adverse reactions listed on 1640 would have been reasonable to warn of at the time of the launch of the Abbrevo; correct? A. Yes.
3 4 5 6 7 8 9 10 11 12 13 14	or not excessive contraction was something more than a hypothesized risk? MR. GAGE: Objection; beyond the scope. Go ahead. THE WITNESS: I don't recall any. BY MR. BARLOW: Q. Doctor, with regard to the other adverse reactions listed on 1640, were all those adverse reactions known by Ethicon to be riskadverse reactions that could occur with the TVT family of products at the time of the launch of the	2 3 4 5 6 7 8 9 10 11 12 13 14	Pyou notified Health Canada that you would include it, but it did not actually appear in the TVT Abbrevo. A. That's right. Q. IFU. A. That's correct. Q. With the exception of the excessive contraction, all of the adverse reactions listed on 1640 would have been reasonable to warn of at the time of the launch of the Abbrevo; correct? A. Yes. Q. It would have been reasonable to warn
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3 4 5 6 7 8 9 10 11 12 13 14 15 16	or not excessive contraction was something more than a hypothesized risk? MR. GAGE: Objection; beyond the scope. Go ahead. THE WITNESS: I don't recall any. BY MR. BARLOW: Q. Doctor, with regard to the other adverse reactions listed on 1640, were all those adverse reactions known by Ethicon to be riskadverse reactions that could occur with the TVT family of products at the time of the launch of the original TVT? A. Yes.	2 3 4 5 6 7 8 9 10 11 12 13 14	BY MR. BARLOW: Q. You notified Health Canada that you would include it, but it did not actually appear in the TVT Abbrevo. A. That's right. Q. IFU. A. That's correct. Q. With the exception of the excessive contraction, all of the adverse reactions listed on 1640 would have been reasonable to warn of at the time of the launch of the Abbrevo; correct? A. Yes. Q. It would have been reasonable to warn of foreign body response resulting in inflammation, extrusion, erosion, exposure, and fistula formation;
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	or not excessive contraction was something more than a hypothesized risk? MR. GAGE: Objection; beyond the scope. Go ahead. THE WITNESS: I don't recall any. BY MR. BARLOW: Q. Doctor, with regard to the other adverse reactions listed on 1640, were all those adverse reactions known by Ethicon to be risk adverse reactions that could occur with the TVT family of products at the time of the launch of the original TVT? A. Yes. Q. Doctor, at the time strike that.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	BY MR. BARLOW: Q. You notified Health Canada that you would include it, but it did not actually appear in the TVT Abbrevo. A. That's right. Q. IFU. A. That's correct. Q. With the exception of the excessive contraction, all of the adverse reactions listed on 1640 would have been reasonable to warn of at the time of the launch of the Abbrevo; correct? A. Yes. Q. It would have been reasonable to warn of foreign body response resulting in inflammation, extrusion, erosion, exposure, and fistula formation; correct?
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3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	or not excessive contraction was something more than a hypothesized risk? MR. GAGE: Objection; beyond the scope. Go ahead. THE WITNESS: I don't recall any. BY MR. BARLOW: Q. Doctor, with regard to the other adverse reactions listed on 1640, were all those adverse reactions known by Ethicon to be risk adverse reactions that could occur with the TVT family of products at the time of the launch of the original TVT? A. Yes. Q. Doctor, at the time strike that. It would have been feasible to warn of all of the risks listed on Exhibit 1640 at the time of the launch of the original TVT, would it have wouldn't it have? A. Feasible	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	BY MR. BARLOW: Q. You notified Health Canada that you would include it, but it did not actually appear in the TVT Abbrevo. A. That's right. Q. IFU. A. That's correct. Q. With the exception of the excessive contraction, all of the adverse reactions listed on 1640 would have been reasonable to warn of at the time of the launch of the Abbrevo; correct? A. Yes. Q. It would have been reasonable to warn of foreign body response resulting in inflammation, extrusion, erosion, exposure, and fistula formation; correct? A. Yes. Q. At the time of the launch of the Abbrevo, it would have been reasonable to warn of mesh extrusion, exposure, and erosion into the vagina and other structures or organs; correct?
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3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	or not excessive contraction was something more than a hypothesized risk? MR. GAGE: Objection; beyond the scope. Go ahead. THE WITNESS: I don't recall any. BY MR. BARLOW: Q. Doctor, with regard to the other adverse reactions listed on 1640, were all those adverse reactions known by Ethicon to be risk adverse reactions that could occur with the TVT family of products at the time of the launch of the original TVT? A. Yes. Q. Doctor, at the time strike that. It would have been feasible to warn of all of the risks listed on Exhibit 1640 at the time of the launch of the original TVT, would it have wouldn't it have? A. Feasible	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	BY MR. BARLOW: Q. You notified Health Canada that you would include it, but it did not actually appear in the TVT Abbrevo. A. That's right. Q. IFU. A. That's correct. Q. With the exception of the excessive contraction, all of the adverse reactions listed on 1640 would have been reasonable to warn of at the time of the launch of the Abbrevo; correct? A. Yes. Q. It would have been reasonable to warn of foreign body response resulting in inflammation, extrusion, erosion, exposure, and fistula formation; correct? A. Yes. Q. At the time of the launch of the Abbrevo, it would have been reasonable to warn of mesh extrusion, exposure, and erosion into the vagina and other structures or organs; correct?

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Page 310 Page 312 1 acute and chronic pain, wouldn't it have? 1 original TVT, it would have been reasonable to warn 2 2 Yes. of pain with intercourse, which in some patients may A. 3 3 Q. It would have been reasonable to warn not resolve; correct? 4 4 A. of pain with intercourse with some patients that may Yes. 5 not resolve at the time of the launch of the TVT At the time of the launch of the Q. 6 6 Abbrevo; correct? original TVT, it would have been reasonable to warn 7 7 of neuromuscular problems, including acute and/or A. Yes. 8 8 O. chronic pain in the groin, thigh, leg, pelvic and/or It would have been reasonable to warn 9 of neuromuscular problems, including acute and/or 9 abdominal area; correct? 10 chronic pain in the groin, thigh, leg, pelvic and 10 Α. Yes. abdominal area at the time of the launch of the TVT 11 At the time of the launch of the 11 O. 12 Abbrevo, wouldn't it have? original TVT, it would have been reasonable to warn 12 13 A. Yes. 13 that adverse reactions to the TVT may require 14 O. And it would have been reasonable to 14 surgical treatment; correct? 15 warn at the time of the launch of the TVT Abbrevo of 15 Yes. I -- you know what? I think I A. spoke too quickly on one of those and I'd like to go 16 the adverse reactions, that they may require 16 17 surgical treatment to cure them; correct? 17 back to the -- the thigh and leg pain for the 18 A. Yes. 18 original TVT. 19 O. It would have been reasonable to warn 19 The original TVT did not involve that 20 20 at the launch of the TVT Abbrevo that one or more area. 21 revision surgeries may be necessary to treat adverse 21 MR. BARLOW: I'm going to object as 22 reactions to the TVT Abbrevo. That would have been 22 nonresponsive and I'll ask you a clean question. 23 23 reasonable to warn of at its launch: correct? THE WITNESS: Okay. 24 24 Α. Yes. BY MR. BARLOW: 25 25 O. It would have also been -- strike Q. At the time of the launch of the Page 311 Page 313 1 that. 1 original TVT, it would have been reasonable to warn 2 2 of neuromuscular problems, including acute and/or It would have been reasonable to warn 3 3 at the time of the launch of the TVT Abbrevo that in chronic pain in the groin and/or pelvic and 4 cases in which Prolene mesh needs to be removed in abdominal area. 4 5 5 part or in whole, significant dissection may be A. Yes. 6 required; correct? 6 O. At the time of the launch of the 7 7 A. Yes. original TVT, it would have been reasonable to have 8 8 O. And, Doctor, just so we have the warned that adverse reactions to the TVT may require 9 9 record clean, at the time of the launch of the surgical treatment; correct? 10 original TVT, it would have been reasonable to warn 10 Α. Yes. of the foreign body response that could result in 11 O. And it would have been -- strike 11 inflammation, extrusion, erosion, exposure, and 12 12 that. 13 fistula formation; correct? 13 It would have been reasonable to warn 14 14 at the time of the launch of the original TVT that A. Yes. 15 O. At the time of the launch of the 15 one or more revision surgeries may be necessary to 16 original TVT, it would have been reasonable to warn 16 treat adverse reactions to the TVT; correct? of mesh extrusion, exposure, erosion into the vagina 17 17 Α. and other structures or organs; correct? 18 18 O. It would have been reasonable to warn 19 19 A. Yes. at the time of the launch of the original TVT that 20 20 in cases where Prolene mesh needs to be removed in O. At the time of the launch of the TVT. 21 it would have been reasonable for Ethicon to warn 21 part or whole, significant dissection may be 22 required; correct? 22 about acute and/or chronic pain in association with the TVT; correct? 23 23 A. Yes. 24 A. Yes. 24 O. And, Doctor, I'm going to go through 25 25 the same questions with the TVT-O and then we'll At the time of the launch of the Q.

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Page 316 Page 314 1 move forward. Okay? 1 TVT-O device, it would have been reasonable for 2 2 Okay. Ethicon to have warned that acute or chronic pain A. 3 3 Q. At the time of the launch of the could result from the device. 4 4 TVT-O, it would have been reasonable for Ethicon to The reason I'm hesitating is because 5 warn that foreign body response to the TVT-O could 5 the device is part of the procedure and it's hard to result in inflammation, extrusion, erosion, 6 6 know what the pain is from, whether it's from the 7 exposure, and fistula formation; correct? 7 device or from the procedure, but --8 8 Doctor, it would have been reasonable A. Yes. 9 O. It was something that was known to 9 to warn that -- at the time of the launch of the 10 Ethicon at the time of the launch of the TVT-O that 10 TVT-O, that use of the product could result in acute 11 the foreign body response to the TVT-O can result in 11 and/or chronic pain. inflammation, extrusion, erosion, exposure, and 12 12 A. Yes. 13 13 fistula formation; correct? O. It would have been reasonable to warn 14 A. Yes. 14 at the time -- strike that. 15 O. It was something that was known to 15 It was known to Ethicon at the time 16 Ethicon at the time of the launch of the TVT-O that 16 of the launch of the TVT-O that pain with 17 mesh extrusion, exposure, and erosion into the 17 intercourse, which in some patients may not resolve, 18 vagina or other structures or organs could occur 18 may result from use of the TVT-O. 19 with the TVT-O; correct? 19 A. Yes. 20 20 A. Yes. O. And it would have been reasonable to 21 O. It would have been reasonable for 21 warn at the time of the launch of the TVT-O that 22 Ethicon to warn the doctors and consumers that mesh 22 pain with intercourse, which in some patients may 23 23 extrusion, exposure, or erosion into the vagina or not resolve, could result from use of the TVT-O; 24 24 other structures or organs could occur with the correct? 25 25 TVT-O at the time of its launch; correct? A. Yes. Page 315 Page 317 1 MR. GAGE: Object to form. 1 O. And it was known to -- strike that. 2 THE WITNESS: Yes. 2 It was known to Ethicon at the time 3 MR. BARLOW: Because of the 3 that the TVT-O was launched that neuromuscular 4 4 objection, let me ask it a different way. problems, including acute and/or chronic pain in the 5 5 BY MR. BARLOW: groin, thigh, leg, pelvic and/or abdominal area 6 Doctor, it would have been reasonable 6 could result from the use of the TVT-O; correct? 7 for Ethicon to warn with regard to the TVT-O at the 7 A. Yes. 8 8 time of its launch that mesh extrusion, exposure, or O. And at the time -- it would have been 9 9 erosion into the vagina or other structures or reasonable to warn at the time of the launch of the 10 organs could occur with the TVT-O; correct? 10 TVT-O that neuromuscular problems, including acute 11 11 and/or chronic pain in the groin, thigh, leg, pelvic A. Yes. and abdominal area could result, correct, from its 12 It was known to Ethicon at the time 12 use? 13 of the launch of the TVT-O that acute and/or chronic 13 14 pain could result from the TVT-O; correct? 14 A. Yes. It was known to Ethicon at the time 15 A. Yes. 15 O. 16 Q. It was also -- well, strike that. 16 of the launch of the TVT-O that the adverse 17 It was reasonable -- it would have 17 reactions to the TVT-O may require surgical been reasonable for Ethicon to warn at the time of 18 treatment: correct? 18 19 19 the launch of the TVT-O that acute and/or chronic Α. Yes. 20 pain could result from the TVT-O; correct? 20 It would have been reasonable for 21 A. From the procedure? Or from the 21 Ethicon to have warned at the time of the launch of 22 22 device? the TVT-O that adverse reactions may require 23 surgical treatment; correct? 23 MR. BARLOW: Object as nonresponsive. 24 BY MR. BARLOW: 24 A. Yes. 25 25 Q. At the time of the launch of the It was known to Ethicon at the time Ο.

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Page 320 Page 318 1 of the launch of the TVT-O that one or more revision 1 It was known to Ethicon at the time 2 2 surgeries may be necessary to treat the adverse of the launch of the original TVT that mesh 3 3 reactions to the TVT-O; correct? extrusion, exposure, or erosion into the vagina or 4 4 other structures or organs could occur as a result Α. Yes. 5 5 Q. And at the time of the launch of the of the use of the TVT; correct? 6 TVT-O, it would have been reasonable for Ethicon to 6 A. Yes. 7 7 warn that one or more revision surgeries may be Q. It was known by Ethicon at the time 8 8 necessary to treat the adverse reactions from its of the launch of the original TVT that acute and/or 9 use: correct? 9 chronic pain could result from its use; correct? 10 Yes. 10 Yes. Α. A. 11 11 O. Doctor, at the time of the launch of It was known by Ethicon at the time 12 the TVT-O, it was known to Ethicon -- strike that. 12 of the launch of the original TVT that pain with 13 I've got a dry mouth. I'm sorry. 13 intercourse, which in some patients may not resolve, 14 MS. KABBASH: Alex, while you've 14 could result from the use of the TVT; correct? 15 stopped, I don't know if we need to go off. There's 15 Α. 16 an attorney who can't dial in because he says the 16 Q. It was known by Ethicon at the time 17 number from yesterday is not working. 17 of the launch of the original TVT that neuromuscular 18 Is there a different number today? 18 problems, including acute and/or chronic pain in the 19 THE VIDEO TECHNICIAN: We'll go off 19 groin, pelvis, and abdominal area could result from 20 20 the record? the use of the TVT; correct? 21 21 A. MS. KABBASH: Yeah. Yes. 22 THE VIDEO TECHNICIAN: The time is 22 Q. It was known by Ethicon at the time 23 23 9:59. We're going off the record. of the launch of the original TVT that the adverse 24 24 reactions that could occur as a result of its use 25 (A discussion off the record 25 may require surgical treatment; correct? Page 319 Page 321 1 occurred.) 1 A. Yes. 2 2 Q. It was known at the time of the 3 3 THE VIDEO TECHNICIAN: The time is launch of the original TVT that one or more revision 4 4 10:02. We're back on the record. surgeries may be necessary to treat the adverse BY MR. BARLOW: 5 5 reactions to the TVT's use; correct? 6 Doctor, now that I've got some water 6 A. Yes. 7 and not choking, we'll take up the questions again. 7 In cases in which -- strike that. Q. 8 8 At the time of the launch of the It was known to Ethicon at the time 9 9 TVT-O, it was known to Ethicon that in cases in of the launch of the original TVT that in cases in 10 which the Prolene mesh needed to be removed in part 10 which the Prolene mesh used in the TVT needed to be 11 or whole, significant dissection may be required; 11 removed in part or whole, significant dissection may 12 12 correct? be required; correct? 13 13 A. Yes. A. Yes. 14 And it would have been reasonable at 14 O. O. Doctor, it was known at the time of 15 the time of the launch of the TVT-O for Ethicon to 15 the launch of the original TVT that even when 16 warn that in cases in which the Prolene mesh needs 16 additional surgeries were performed, that the to be removed in part or whole, significant 17 adverse reactions and the symptoms related to them 17 18 dissection may be required; correct? may not resolve; correct? 18 19 19 A. Yes. Α. That's correct. 20 20 O. And, Doctor, at the time of the And that -- it was known at the time 21 launch of the TVT -- the original TVT, it was known 21 of the launch of the TVT-O that even with additional 22 22 to Ethicon that the foreign body response could surgeries to treat the adverse reactions that may occur with the TVT-O, those adverse reactions or the result in inflammation, extrusion, erosion, 23 23 exposure, and fistula formation; correct? 24 24 symptoms related to them may not resolve; correct? 25 25 That's correct. A. Yes.

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	Page 322		Page 324
1	Q. And it was known at the time of the	1	A. Yes.
2	launch of the TVT Abbrevo that even with surgeries	2	Q. It was known by Ethicon at the time
3	to correct the adverse reactions to the TVT Abbrevo,	3	of the launch of the original TVT-O that de novo
4	that the symptoms or the adverse reactions may not	4	urinary retention could result from its use;
5	resolve; correct?	5	correct?
6	A. Yes.	6	A. Yes.
7	Q. And it would have been reasonable at	7	Q. It was known by Ethicon at the time
8	the time of the launch of the TVT Abbrevo to warn	8	of the launch of the original TVT that urinary
9	about the possibility that additional surgeries may	9	obstruction de novo urinary obstruction could
10	not cure the symptoms or adverse reactions; correct?	10	result from its use; correct?
11	A. Yes.	11	A. Yes.
12	Q. It would have been reasonable to warn	12	Q. It was known at the time of the
13	at the time of the launch of the original TVT that	13	launch of the original TVT that de novo voiding
14	additional surgeries may not resolve the adverse	14	dysfunction could result from its use; correct?
15	reactions or the related symptoms to the use of the	15	A. Yes.
16	TVT; correct?	16	Q. Doctor, at the time of the launch of
17	A. Correct.	17	the TVT-O, it was known that de novo urge
18	Q. And it would have been reasonable for	18	incontinence could result from its use; correct?
19	strike that.	19	A. Yes.
20	At the time of the launch of the	20	Q. At the time of the launch of the
21	TVT-O, it would have been reasonable for Ethicon to	21	TVT-O, it was known that de novo urinary infrequency
22	warn that additional surgeries to treat adverse	22	urinary frequency could result from its use;
23	reactions may not resolve those adverse reactions or	23	correct?
24	symptoms; correct?	24	A. Yes.
25	A. Correct.	25	Q. At the time of the launch of the
	702		
	Page 323		Page 325
1	Q. Doctor, let me turn your attention to	1	original of the TVT-O, it was known that de novo
2	Q. Doctor, let me turn your attention to Exhibit 1641.	2	original of the TVT-O, it was known that de novo urinary retention could result from its use,
2	Q. Doctor, let me turn your attention to Exhibit 1641. A. Okay.	2	original of the TVT-O, it was known that de novo urinary retention could result from its use, correct, by Ethicon?
2 3 4	 Q. Doctor, let me turn your attention to Exhibit 1641. A. Okay. Q. Doctor, at the time of the launch of 	2 3 4	original of the TVT-O, it was known that de novo urinary retention could result from its use, correct, by Ethicon? A. Yes.
2 3 4 5	 Q. Doctor, let me turn your attention to Exhibit 1641. A. Okay. Q. Doctor, at the time of the launch of the original TVT, it was known to Ethicon that urge 	2 3 4 5	original of the TVT-O, it was known that de novo urinary retention could result from its use, correct, by Ethicon? A. Yes. Q. That was known.
2 3 4 5 6	Q. Doctor, let me turn your attention to Exhibit 1641. A. Okay. Q. Doctor, at the time of the launch of the original TVT, it was known to Ethicon that urge incontinence could result from its use; correct?	2 3 4 5 6	original of the TVT-O, it was known that de novo urinary retention could result from its use, correct, by Ethicon? A. Yes. Q. That was known. It was known by Ethicon at the time
2 3 4 5 6 7	 Q. Doctor, let me turn your attention to Exhibit 1641. A. Okay. Q. Doctor, at the time of the launch of the original TVT, it was known to Ethicon that urge incontinence could result from its use; correct? A. Yes. 	2 3 4 5 6 7	original of the TVT-O, it was known that de novo urinary retention could result from its use, correct, by Ethicon? A. Yes. Q. That was known. It was known by Ethicon at the time of the launch of TVT-O that de novo urinary
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2 3 4 5 6 7 8 9	Q. Doctor, let me turn your attention to Exhibit 1641. A. Okay. Q. Doctor, at the time of the launch of the original TVT, it was known to Ethicon that urge incontinence could result from its use; correct? A. Yes. Q. At the time of the launch of the original TVT, it was known to Ethicon that urinary frequency could result from the TVT's use; correct?	2 3 4 5 6 7 8 9	original of the TVT-O, it was known that de novo urinary retention could result from its use, correct, by Ethicon? A. Yes. Q. That was known. It was known by Ethicon at the time of the launch of TVT-O that de novo urinary obstruction could occur from its use; correct? A. Yes. Q. And it was known by Ethicon at the
2 3 4 5 6 7 8 9 10	Q. Doctor, let me turn your attention to Exhibit 1641. A. Okay. Q. Doctor, at the time of the launch of the original TVT, it was known to Ethicon that urge incontinence could result from its use; correct? A. Yes. Q. At the time of the launch of the original TVT, it was known to Ethicon that urinary frequency could result from the TVT's use; correct? A. Yes.	2 3 4 5 6 7 8 9 10	original of the TVT-O, it was known that de novo urinary retention could result from its use, correct, by Ethicon? A. Yes. Q. That was known. It was known by Ethicon at the time of the launch of TVT-O that de novo urinary obstruction could occur from its use; correct? A. Yes. Q. And it was known by Ethicon at the time of the TVT-O's launch that de novo voiding
2 3 4 5 6 7 8 9 10 11 12	Q. Doctor, let me turn your attention to Exhibit 1641. A. Okay. Q. Doctor, at the time of the launch of the original TVT, it was known to Ethicon that urge incontinence could result from its use; correct? A. Yes. Q. At the time of the launch of the original TVT, it was known to Ethicon that urinary frequency could result from the TVT's use; correct? A. Yes. Q. And this would be de novo urinary	2 3 4 5 6 7 8 9 10 11	original of the TVT-O, it was known that de novo urinary retention could result from its use, correct, by Ethicon? A. Yes. Q. That was known. It was known by Ethicon at the time of the launch of TVT-O that de novo urinary obstruction could occur from its use; correct? A. Yes. Q. And it was known by Ethicon at the time of the TVT-O's launch that de novo voiding dysfunction could result from its use; correct?
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	Q. Doctor, let me turn your attention to Exhibit 1641. A. Okay. Q. Doctor, at the time of the launch of the original TVT, it was known to Ethicon that urge incontinence could result from its use; correct? A. Yes. Q. At the time of the launch of the original TVT, it was known to Ethicon that urinary frequency could result from the TVT's use; correct? A. Yes. Q. And this would be de novo urinary frequency. Right? A. Yes. Q. And, Doctor, let me go back and clean it up. At the time of the launch of the original TVT, it was known to Ethicon that de novo urge incontinence could result from its use;	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	original of the TVT-O, it was known that de novo urinary retention could result from its use, correct, by Ethicon? A. Yes. Q. That was known. It was known by Ethicon at the time of the launch of TVT-O that de novo urinary obstruction could occur from its use; correct? A. Yes. Q. And it was known by Ethicon at the time of the TVT-O's launch that de novo voiding dysfunction could result from its use; correct? A. Yes. Q. Doctor, at the time of the launch of the original TVT, it would have been reasonable for Ethicon to warn that de novo urge incontinence could result from its use; correct? A. Yes. Q. At the time of the launch of the
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Q. Doctor, let me turn your attention to Exhibit 1641. A. Okay. Q. Doctor, at the time of the launch of the original TVT, it was known to Ethicon that urge incontinence could result from its use; correct? A. Yes. Q. At the time of the launch of the original TVT, it was known to Ethicon that urinary frequency could result from the TVT's use; correct? A. Yes. Q. And this would be de novo urinary frequency. Right? A. Yes. Q. And, Doctor, let me go back and clean it up. At the time of the launch of the original TVT, it was known to Ethicon that de novo urge incontinence could result from its use; correct?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	original of the TVT-O, it was known that de novo urinary retention could result from its use, correct, by Ethicon? A. Yes. Q. That was known. It was known by Ethicon at the time of the launch of TVT-O that de novo urinary obstruction could occur from its use; correct? A. Yes. Q. And it was known by Ethicon at the time of the TVT-O's launch that de novo voiding dysfunction could result from its use; correct? A. Yes. Q. Doctor, at the time of the launch of the original TVT, it would have been reasonable for Ethicon to warn that de novo urge incontinence could result from its use; correct? A. Yes. Q. At the time of the launch of the original TVT, it would have been reasonable for
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. Doctor, let me turn your attention to Exhibit 1641. A. Okay. Q. Doctor, at the time of the launch of the original TVT, it was known to Ethicon that urge incontinence could result from its use; correct? A. Yes. Q. At the time of the launch of the original TVT, it was known to Ethicon that urinary frequency could result from the TVT's use; correct? A. Yes. Q. And this would be de novo urinary frequency. Right? A. Yes. Q. And, Doctor, let me go back and clean it up. At the time of the launch of the original TVT, it was known to Ethicon that de novo urge incontinence could result from its use; correct? A. Yes.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	original of the TVT-O, it was known that de novo urinary retention could result from its use, correct, by Ethicon? A. Yes. Q. That was known. It was known by Ethicon at the time of the launch of TVT-O that de novo urinary obstruction could occur from its use; correct? A. Yes. Q. And it was known by Ethicon at the time of the TVT-O's launch that de novo voiding dysfunction could result from its use; correct? A. Yes. Q. Doctor, at the time of the launch of the original TVT, it would have been reasonable for Ethicon to warn that de novo urge incontinence could result from its use; correct? A. Yes. Q. At the time of the launch of the original TVT, it would have been reasonable for Ethicon to warn that de novo urinary frequency could
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. Doctor, let me turn your attention to Exhibit 1641. A. Okay. Q. Doctor, at the time of the launch of the original TVT, it was known to Ethicon that urge incontinence could result from its use; correct? A. Yes. Q. At the time of the launch of the original TVT, it was known to Ethicon that urinary frequency could result from the TVT's use; correct? A. Yes. Q. And this would be de novo urinary frequency. Right? A. Yes. Q. And, Doctor, let me go back and clean it up. At the time of the launch of the original TVT, it was known to Ethicon that de novo urge incontinence could result from its use; correct? A. Yes. Q. And at the time of the launch of the	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	original of the TVT-O, it was known that de novo urinary retention could result from its use, correct, by Ethicon? A. Yes. Q. That was known. It was known by Ethicon at the time of the launch of TVT-O that de novo urinary obstruction could occur from its use; correct? A. Yes. Q. And it was known by Ethicon at the time of the TVT-O's launch that de novo voiding dysfunction could result from its use; correct? A. Yes. Q. Doctor, at the time of the launch of the original TVT, it would have been reasonable for Ethicon to warn that de novo urge incontinence could result from its use; correct? A. Yes. Q. At the time of the launch of the original TVT, it would have been reasonable for Ethicon to warn that de novo urinary frequency could result from its use; correct?
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. Doctor, let me turn your attention to Exhibit 1641. A. Okay. Q. Doctor, at the time of the launch of the original TVT, it was known to Ethicon that urge incontinence could result from its use; correct? A. Yes. Q. At the time of the launch of the original TVT, it was known to Ethicon that urinary frequency could result from the TVT's use; correct? A. Yes. Q. And this would be de novo urinary frequency. Right? A. Yes. Q. And, Doctor, let me go back and clean it up. At the time of the launch of the original TVT, it was known to Ethicon that de novo urge incontinence could result from its use; correct? A. Yes. Q. And at the time of the launch of the	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	original of the TVT-O, it was known that de novo urinary retention could result from its use, correct, by Ethicon? A. Yes. Q. That was known. It was known by Ethicon at the time of the launch of TVT-O that de novo urinary obstruction could occur from its use; correct? A. Yes. Q. And it was known by Ethicon at the time of the TVT-O's launch that de novo voiding dysfunction could result from its use; correct? A. Yes. Q. Doctor, at the time of the launch of the original TVT, it would have been reasonable for Ethicon to warn that de novo urge incontinence could result from its use; correct? A. Yes. Q. At the time of the launch of the original TVT, it would have been reasonable for Ethicon to warn that de novo urinary frequency could result from its use; correct?

9 (Pages 322 to 325)

	Page 326		Page 328
1	reasonable for Ethicon to have warned that de novo	1	A. Yes.
2	urinary retention could result from its use;	2	Q. At the time of the launch of the
3	correct?	3	Abbrevo, it was known by Ethicon that de novo
4	A. Yes.	4	urinary retention could result from its use;
5	Q. At the time of the launch of the	5	correct?
6	original TVT, it would have been reasonable for	6	A. Yes.
7	Ethicon to have warned that de novo urinary	7	Q. At the time of the launch of the TVT
8	obstruction could result from its use; correct?	8	Abbrevo, it was known that de novo urinary
9	A. Yes.	9	obstruction could result from its use; correct?
10	Q. At the time of the launch of the	10	A. Yes.
11	original TVT, it would have been reasonable for	11	Q. At the time of the launch of the TVT
12	Ethicon to have warned that de novo voiding	12	Abbrevo, it was known by Ethicon that de novo
13	dysfunction could result from its use; correct?	13	voiding dysfunction could result from its use;
14	A. Yes.	14	correct?
15	Q. Doctor, at the time of the launch of	15	A. Yes.
16	the TVT-O, it would have been reasonable for Ethicon		Q. Doctor, at the time of the launch of
17	to warn that de novo urge incontinence could result	17	the Abbrevo, it would have been reasonable for
18	from its use; correct?	18	Ethicon to warn that de novo urge incontinence could
19	A. Yes.	19	result from its use; correct?
20	Q. At the time of the launch of the	20	A. Yes.
21	TVT-O, it would have been reasonable for Ethicon to	21	Q. At the time of the launch of the TVT
22	have warned that de novo urinary frequency could	22	Abbrevo, it would have been reasonable for Ethicon
23	result from its use; correct?	23	to warn that de novo urinary frequency could result;
24	A. Yes.	24	correct?
25	Q. At the time of the launch of the	25	A. Yes.
	Page 327		D 200
			Page 329
1	TVT-O, it would have been reasonable for Ethicon to	1	Q. At the time of the launch of the TVT
2	TVT-O, it would have been reasonable for Ethicon to have warned that de novo urinary retention could	2	Q. At the time of the launch of the TVT Abbrevo, it would have been reasonable for Ethicon
2	TVT-O, it would have been reasonable for Ethicon to have warned that de novo urinary retention could result from its use; correct?	2	Q. At the time of the launch of the TVT Abbrevo, it would have been reasonable for Ethicon to have warned that de novo urinary retention could
2 3 4	TVT-O, it would have been reasonable for Ethicon to have warned that de novo urinary retention could result from its use; correct? A. Yes.	2 3 4	Q. At the time of the launch of the TVT Abbrevo, it would have been reasonable for Ethicon to have warned that de novo urinary retention could result from the Abbrevo; correct?
2 3 4 5	TVT-O, it would have been reasonable for Ethicon to have warned that de novo urinary retention could result from its use; correct? A. Yes. Q. At the time of the launch of the	2 3 4 5	Q. At the time of the launch of the TVT Abbrevo, it would have been reasonable for Ethicon to have warned that de novo urinary retention could result from the Abbrevo; correct? A. Yes.
2 3 4 5 6	TVT-O, it would have been reasonable for Ethicon to have warned that de novo urinary retention could result from its use; correct? A. Yes. Q. At the time of the launch of the TVT-O, it would have been reasonable for Ethicon to	2 3 4 5 6	Q. At the time of the launch of the TVT Abbrevo, it would have been reasonable for Ethicon to have warned that de novo urinary retention could result from the Abbrevo; correct? A. Yes. Q. At the time of the launch of the TVT
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2 3 4 5 6 7 8	TVT-O, it would have been reasonable for Ethicon to have warned that de novo urinary retention could result from its use; correct? A. Yes. Q. At the time of the launch of the TVT-O, it would have been reasonable for Ethicon to have warned that de novo urinary obstruction could result from its use; correct?	2 3 4 5 6 7 8	Q. At the time of the launch of the TVT Abbrevo, it would have been reasonable for Ethicon to have warned that de novo urinary retention could result from the Abbrevo; correct? A. Yes. Q. At the time of the launch of the TVT Abbrevo, it would have been reasonable for Ethicon to warn that de novo urinary obstruction could
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2 3 4 5 6 7 8 9 10	TVT-O, it would have been reasonable for Ethicon to have warned that de novo urinary retention could result from its use; correct? A. Yes. Q. At the time of the launch of the TVT-O, it would have been reasonable for Ethicon to have warned that de novo urinary obstruction could result from its use; correct? A. Yes. Q. At the time of the launch of the TVT-O, it would have been reasonable for Ethicon to	2 3 4 5 6 7 8 9 10	Q. At the time of the launch of the TVT Abbrevo, it would have been reasonable for Ethicon to have warned that de novo urinary retention could result from the Abbrevo; correct? A. Yes. Q. At the time of the launch of the TVT Abbrevo, it would have been reasonable for Ethicon to warn that de novo urinary obstruction could result from the Abbrevo; correct? A. Yes. Q. At the time of the launch of the TVT
2 3 4 5 6 7 8 9 10 11 12	TVT-O, it would have been reasonable for Ethicon to have warned that de novo urinary retention could result from its use; correct? A. Yes. Q. At the time of the launch of the TVT-O, it would have been reasonable for Ethicon to have warned that de novo urinary obstruction could result from its use; correct? A. Yes. Q. At the time of the launch of the TVT-O, it would have been reasonable for Ethicon to warn of de novo voiding dysfunction resulting from	2 3 4 5 6 7 8 9 10 11	Q. At the time of the launch of the TVT Abbrevo, it would have been reasonable for Ethicon to have warned that de novo urinary retention could result from the Abbrevo; correct? A. Yes. Q. At the time of the launch of the TVT Abbrevo, it would have been reasonable for Ethicon to warn that de novo urinary obstruction could result from the Abbrevo; correct? A. Yes. Q. At the time of the launch of the TVT Abbrevo, it would have been reasonable for Ethicon
2 3 4 5 6 7 8 9 10 11 12 13	TVT-O, it would have been reasonable for Ethicon to have warned that de novo urinary retention could result from its use; correct? A. Yes. Q. At the time of the launch of the TVT-O, it would have been reasonable for Ethicon to have warned that de novo urinary obstruction could result from its use; correct? A. Yes. Q. At the time of the launch of the TVT-O, it would have been reasonable for Ethicon to warn of de novo voiding dysfunction resulting from its use; correct?	2 3 4 5 6 7 8 9 10 11 12 13	Q. At the time of the launch of the TVT Abbrevo, it would have been reasonable for Ethicon to have warned that de novo urinary retention could result from the Abbrevo; correct? A. Yes. Q. At the time of the launch of the TVT Abbrevo, it would have been reasonable for Ethicon to warn that de novo urinary obstruction could result from the Abbrevo; correct? A. Yes. Q. At the time of the launch of the TVT Abbrevo, it would have been reasonable for Ethicon to have warned that de novo voiding dysfunction
2 3 4 5 6 7 8 9 10 11 12 13 14	TVT-O, it would have been reasonable for Ethicon to have warned that de novo urinary retention could result from its use; correct? A. Yes. Q. At the time of the launch of the TVT-O, it would have been reasonable for Ethicon to have warned that de novo urinary obstruction could result from its use; correct? A. Yes. Q. At the time of the launch of the TVT-O, it would have been reasonable for Ethicon to warn of de novo voiding dysfunction resulting from its use; correct? A. Yes.	2 3 4 5 6 7 8 9 10 11 12 13 14	Q. At the time of the launch of the TVT Abbrevo, it would have been reasonable for Ethicon to have warned that de novo urinary retention could result from the Abbrevo; correct? A. Yes. Q. At the time of the launch of the TVT Abbrevo, it would have been reasonable for Ethicon to warn that de novo urinary obstruction could result from the Abbrevo; correct? A. Yes. Q. At the time of the launch of the TVT Abbrevo, it would have been reasonable for Ethicon to have warned that de novo voiding dysfunction could result from the Abbrevo; correct?
2 3 4 5 6 7 8 9 10 11 12 13 14 15	TVT-O, it would have been reasonable for Ethicon to have warned that de novo urinary retention could result from its use; correct? A. Yes. Q. At the time of the launch of the TVT-O, it would have been reasonable for Ethicon to have warned that de novo urinary obstruction could result from its use; correct? A. Yes. Q. At the time of the launch of the TVT-O, it would have been reasonable for Ethicon to warn of de novo voiding dysfunction resulting from its use; correct? A. Yes. Q. Doctor, at the time of the launch of	2 3 4 5 6 7 8 9 10 11 12 13 14 15	Q. At the time of the launch of the TVT Abbrevo, it would have been reasonable for Ethicon to have warned that de novo urinary retention could result from the Abbrevo; correct? A. Yes. Q. At the time of the launch of the TVT Abbrevo, it would have been reasonable for Ethicon to warn that de novo urinary obstruction could result from the Abbrevo; correct? A. Yes. Q. At the time of the launch of the TVT Abbrevo, it would have been reasonable for Ethicon to have warned that de novo voiding dysfunction could result from the Abbrevo; correct? A. Yes.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	TVT-O, it would have been reasonable for Ethicon to have warned that de novo urinary retention could result from its use; correct? A. Yes. Q. At the time of the launch of the TVT-O, it would have been reasonable for Ethicon to have warned that de novo urinary obstruction could result from its use; correct? A. Yes. Q. At the time of the launch of the TVT-O, it would have been reasonable for Ethicon to warn of de novo voiding dysfunction resulting from its use; correct? A. Yes. Q. Doctor, at the time of the launch of the Abbrevo, it would have been reasonable strike that.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	Q. At the time of the launch of the TVT Abbrevo, it would have been reasonable for Ethicon to have warned that de novo urinary retention could result from the Abbrevo; correct? A. Yes. Q. At the time of the launch of the TVT Abbrevo, it would have been reasonable for Ethicon to warn that de novo urinary obstruction could result from the Abbrevo; correct? A. Yes. Q. At the time of the launch of the TVT Abbrevo, it would have been reasonable for Ethicon to have warned that de novo voiding dysfunction could result from the Abbrevo; correct? A. Yes. Q. Okay. Doctor, of the adverse reactions
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	TVT-O, it would have been reasonable for Ethicon to have warned that de novo urinary retention could result from its use; correct? A. Yes. Q. At the time of the launch of the TVT-O, it would have been reasonable for Ethicon to have warned that de novo urinary obstruction could result from its use; correct? A. Yes. Q. At the time of the launch of the TVT-O, it would have been reasonable for Ethicon to warn of de novo voiding dysfunction resulting from its use; correct? A. Yes. Q. Doctor, at the time of the launch of the Abbrevo, it would have been reasonable strike that. At the time of the launch of the	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q. At the time of the launch of the TVT Abbrevo, it would have been reasonable for Ethicon to have warned that de novo urinary retention could result from the Abbrevo; correct? A. Yes. Q. At the time of the launch of the TVT Abbrevo, it would have been reasonable for Ethicon to warn that de novo urinary obstruction could result from the Abbrevo; correct? A. Yes. Q. At the time of the launch of the TVT Abbrevo, it would have been reasonable for Ethicon to have warned that de novo voiding dysfunction could result from the Abbrevo; correct? A. Yes. Q. Okay. Doctor, of the adverse reactions listed in 1640, I want you to compare that to
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	TVT-O, it would have been reasonable for Ethicon to have warned that de novo urinary retention could result from its use; correct? A. Yes. Q. At the time of the launch of the TVT-O, it would have been reasonable for Ethicon to have warned that de novo urinary obstruction could result from its use; correct? A. Yes. Q. At the time of the launch of the TVT-O, it would have been reasonable for Ethicon to warn of de novo voiding dysfunction resulting from its use; correct? A. Yes. Q. Doctor, at the time of the launch of the Abbrevo, it would have been reasonable strike that. At the time of the launch of the Abbrevo, it was known to Ethicon that de novo urge	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	Q. At the time of the launch of the TVT Abbrevo, it would have been reasonable for Ethicon to have warned that de novo urinary retention could result from the Abbrevo; correct? A. Yes. Q. At the time of the launch of the TVT Abbrevo, it would have been reasonable for Ethicon to warn that de novo urinary obstruction could result from the Abbrevo; correct? A. Yes. Q. At the time of the launch of the TVT Abbrevo, it would have been reasonable for Ethicon to have warned that de novo voiding dysfunction could result from the Abbrevo; correct? A. Yes. Q. Okay. Doctor, of the adverse reactions listed in 1640, I want you to compare that to Exhibit 1656. Okay? The TVT Abbrevo IFU?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	TVT-O, it would have been reasonable for Ethicon to have warned that de novo urinary retention could result from its use; correct? A. Yes. Q. At the time of the launch of the TVT-O, it would have been reasonable for Ethicon to have warned that de novo urinary obstruction could result from its use; correct? A. Yes. Q. At the time of the launch of the TVT-O, it would have been reasonable for Ethicon to warn of de novo voiding dysfunction resulting from its use; correct? A. Yes. Q. Doctor, at the time of the launch of the Abbrevo, it would have been reasonable strike that. At the time of the launch of the Abbrevo, it was known to Ethicon that de novo urge incontinence could result from its use; correct?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Q. At the time of the launch of the TVT Abbrevo, it would have been reasonable for Ethicon to have warned that de novo urinary retention could result from the Abbrevo; correct? A. Yes. Q. At the time of the launch of the TVT Abbrevo, it would have been reasonable for Ethicon to warn that de novo urinary obstruction could result from the Abbrevo; correct? A. Yes. Q. At the time of the launch of the TVT Abbrevo, it would have been reasonable for Ethicon to have warned that de novo voiding dysfunction could result from the Abbrevo; correct? A. Yes. Q. Okay. Doctor, of the adverse reactions listed in 1640, I want you to compare that to Exhibit 1656. Okay? The TVT Abbrevo IFU? A. Yes.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	TVT-O, it would have been reasonable for Ethicon to have warned that de novo urinary retention could result from its use; correct? A. Yes. Q. At the time of the launch of the TVT-O, it would have been reasonable for Ethicon to have warned that de novo urinary obstruction could result from its use; correct? A. Yes. Q. At the time of the launch of the TVT-O, it would have been reasonable for Ethicon to warn of de novo voiding dysfunction resulting from its use; correct? A. Yes. Q. Doctor, at the time of the launch of the Abbrevo, it would have been reasonable strike that. At the time of the launch of the Abbrevo, it was known to Ethicon that de novo urge incontinence could result from its use; correct? A. Yes.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. At the time of the launch of the TVT Abbrevo, it would have been reasonable for Ethicon to have warned that de novo urinary retention could result from the Abbrevo; correct? A. Yes. Q. At the time of the launch of the TVT Abbrevo, it would have been reasonable for Ethicon to warn that de novo urinary obstruction could result from the Abbrevo; correct? A. Yes. Q. At the time of the launch of the TVT Abbrevo, it would have been reasonable for Ethicon to have warned that de novo voiding dysfunction could result from the Abbrevo; correct? A. Yes. Q. Okay. Doctor, of the adverse reactions listed in 1640, I want you to compare that to Exhibit 1656. Okay? The TVT Abbrevo IFU? A. Yes. Q. Are all of the adverse reactions
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	TVT-O, it would have been reasonable for Ethicon to have warned that de novo urinary retention could result from its use; correct? A. Yes. Q. At the time of the launch of the TVT-O, it would have been reasonable for Ethicon to have warned that de novo urinary obstruction could result from its use; correct? A. Yes. Q. At the time of the launch of the TVT-O, it would have been reasonable for Ethicon to warn of de novo voiding dysfunction resulting from its use; correct? A. Yes. Q. Doctor, at the time of the launch of the Abbrevo, it would have been reasonable strike that. At the time of the launch of the Abbrevo, it was known to Ethicon that de novo urge incontinence could result from its use; correct? A. Yes. Q. At the time of the launch of the	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. At the time of the launch of the TVT Abbrevo, it would have been reasonable for Ethicon to have warned that de novo urinary retention could result from the Abbrevo; correct? A. Yes. Q. At the time of the launch of the TVT Abbrevo, it would have been reasonable for Ethicon to warn that de novo urinary obstruction could result from the Abbrevo; correct? A. Yes. Q. At the time of the launch of the TVT Abbrevo, it would have been reasonable for Ethicon to have warned that de novo voiding dysfunction could result from the Abbrevo; correct? A. Yes. Q. Okay. Doctor, of the adverse reactions listed in 1640, I want you to compare that to Exhibit 1656. Okay? The TVT Abbrevo IFU? A. Yes. Q. Are all of the adverse reactions listed in 1640, do they appear in 1656?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	TVT-O, it would have been reasonable for Ethicon to have warned that de novo urinary retention could result from its use; correct? A. Yes. Q. At the time of the launch of the TVT-O, it would have been reasonable for Ethicon to have warned that de novo urinary obstruction could result from its use; correct? A. Yes. Q. At the time of the launch of the TVT-O, it would have been reasonable for Ethicon to warn of de novo voiding dysfunction resulting from its use; correct? A. Yes. Q. Doctor, at the time of the launch of the Abbrevo, it would have been reasonable strike that. At the time of the launch of the Abbrevo, it was known to Ethicon that de novo urge incontinence could result from its use; correct? A. Yes. Q. At the time of the launch of the Abbrevo, it was known to Ethicon that de novo	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q. At the time of the launch of the TVT Abbrevo, it would have been reasonable for Ethicon to have warned that de novo urinary retention could result from the Abbrevo; correct? A. Yes. Q. At the time of the launch of the TVT Abbrevo, it would have been reasonable for Ethicon to warn that de novo urinary obstruction could result from the Abbrevo; correct? A. Yes. Q. At the time of the launch of the TVT Abbrevo, it would have been reasonable for Ethicon to have warned that de novo voiding dysfunction could result from the Abbrevo; correct? A. Yes. Q. Okay. Doctor, of the adverse reactions listed in 1640, I want you to compare that to Exhibit 1656. Okay? The TVT Abbrevo IFU? A. Yes. Q. Are all of the adverse reactions listed in 1640, do they appear in 1656? A. Mesh contraction does not. The
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	TVT-O, it would have been reasonable for Ethicon to have warned that de novo urinary retention could result from its use; correct? A. Yes. Q. At the time of the launch of the TVT-O, it would have been reasonable for Ethicon to have warned that de novo urinary obstruction could result from its use; correct? A. Yes. Q. At the time of the launch of the TVT-O, it would have been reasonable for Ethicon to warn of de novo voiding dysfunction resulting from its use; correct? A. Yes. Q. Doctor, at the time of the launch of the Abbrevo, it would have been reasonable strike that. At the time of the launch of the Abbrevo, it was known to Ethicon that de novo urge incontinence could result from its use; correct? A. Yes. Q. At the time of the launch of the	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. At the time of the launch of the TVT Abbrevo, it would have been reasonable for Ethicon to have warned that de novo urinary retention could result from the Abbrevo; correct? A. Yes. Q. At the time of the launch of the TVT Abbrevo, it would have been reasonable for Ethicon to warn that de novo urinary obstruction could result from the Abbrevo; correct? A. Yes. Q. At the time of the launch of the TVT Abbrevo, it would have been reasonable for Ethicon to have warned that de novo voiding dysfunction could result from the Abbrevo; correct? A. Yes. Q. Okay. Doctor, of the adverse reactions listed in 1640, I want you to compare that to Exhibit 1656. Okay? The TVT Abbrevo IFU? A. Yes. Q. Are all of the adverse reactions listed in 1640, do they appear in 1656?

10 (Pages 326 to 329)

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                                                                                                        Page 332
               With the exception of contraction, do
1
                                                           1
                                                                        MR. BARLOW: Well, I'm not quoting
2
                                                           2
     all of the adverse reactions listed on 1640 appear
                                                               it. I'm just asking if those appear in there.
3
                                                           3
                                                                        MR. GAGE: Oh, oh, oh, oh, oh. Okay.
     in the Abbrevo?
4
                                                           4
                                                               So you have to listen very carefully because I don't
         A.
               Yes.
5
               And with regard to contraction,
                                                           5
                                                               think you understood what he was asking you.
         Q.
                                                           6
6
     Ethicon informed Health Canada that contraction --
                                                                        All right.
7
                                                           7
     excess contraction would be included, but that has
                                                                        MR. FREESE: I think you're the one
8
                                                           8
                                                               that didn't understand. I understood and I think
     not yet occurred; correct?
9
         A.
               Yes.
                                                           9
                                                                the doctor understood.
10
         Q.
               So, Doctor, I guess it makes it -- so
                                                          10
                                                                        MR. GAGE: No, he said -- but he
11
     the record's clean, just let me quickly do this:
                                                          11
                                                               answered, yes, it does appear.
    Foreign body response resulting in inflammation,
                                                                        MR. BARLOW: It does.
12
                                                          12
13
     extrusion, erosion, exposure, and fistula formation
                                                          13
                                                                        MR. FREESE: It does.
14
     appears in the current TVT Abbrevo, which is Exhibit
                                                          14
                                                                        THE WITNESS: Not --
15
     1656; correct?
                                                          15
                                                                        MR. GAGE: Not some of the words you
16
         A. Yes.
                                                          16
                                                               had in the question. Anyway, I'm -- look, if I
17
                                                          17
                                                               messed it up, I'm sorry. I'm -- go ahead.
              (Pause.)
18
     BY MR. BARLOW:
                                                          18
                                                                        THE WITNESS: Okay.
19
               Doctor, foreign body response
                                                          19
                                                                        MR. GAGE: You now have your eyes on
                                                          20
20
    resulting in inflammation, extrusion, erosion,
                                                               the language and he can ask you the question.
21
     exposure, and fistula formation appears in the
                                                          21
                                                                        THE WITNESS: Okay.
22
     current TVT Abbrevo IFU, which is Exhibit 1656;
                                                          22
                                                                        MR. GAGE: Okay.
                                                          23
23
                                                               BY MR. BARLOW:
    correct?
                                                          24
24
         A.
               Yes.
                                                                         Okay. Doctor, foreign -- there is a
                                                               foreign body response that could result in
25
              MR. GAGE: Hang on. You --
                                                          25
                                                                                                        Page 333
                                              Page 331
1
             MR. BARLOW: Or is that incorrect?
                                                           1
                                                               extrusion, erosion, exposure, fistula formation,
2
             MR. GAGE: I don't think he -- could
                                                           2
                                                               and/or inflammation appears in the -- the current
                                                           3
3
                                                                TVT Abbrevo IFU; correct?
     you -- let him find --
                                                           4
4
             MR. BARLOW: Sure.
                                                                          Yes.
                                                                    A.
                                                           5
                                                                          And it appears under the -- in the
5
             MR. GAGE: -- where it is because I'm
                                                                    Q.
6
    not sure he knows -- he's struggling to find it.
                                                           6
                                                               adverse reactions section; correct?
7
             MR. BARLOW: Let me see if I can find
                                                           7
                                                                   A.
                                                                          Yes.
                                                           8
8
                                                                    O.
                                                                          Doctor, on the -- with the exception
    it.
9
                                                           9
                                                               of the excess contraction, which we've already
             MR. GAGE: No, I don't -- that's not
10
    his question, though.
                                                          10
                                                               discussed, do all of the adverse reactions listed on
             THE WITNESS: Did I misunderstand
                                                          11
                                                                1640 appear in the current TVT Abbrevo IFU?
11
12
                                                          12
                                                                         Just give me a moment.
    your question?
                                                                    A.
13
                                                          13
             MR. GAGE: Yeah.
                                                                    Q.
                                                                          Sure.
14
                                                          14
             THE WITNESS: Maybe I ought to listen
                                                                    A.
                                                                          Yes.
15
                                                          15
                                                                          And, Doctor, turning to page --
    to your question again.
                                                                    O.
16
             MR. BARLOW: Okay.
                                                          16
                                                                strike that -- Exhibit 1641, do all of the TVT
              THE WITNESS: I think it's the second
                                                          17
                                                               urinary adverse reactions listed there appear in the
17
                                                               current TVT Abbrevo IFU?
                                                          18
18
     adverse reaction.
19
             (Pause.)
                                                          19
                                                                   Α.
                                                                         Yes.
20
             MR. BARLOW: I think it's the third
                                                          20
     bullet point under adverse reactions.
21
                                                          21
                                                                        (Deposition Exhibit No. P-1657,
                                                          22
22
             MR. GAGE: Okay. And I think what
                                                                     9/10/10-11/27/14 TVT Abbrevo IFU,
     got me was that your -- the actual text of your
                                                          23
23
                                                                     ETH.MESH.02341203 through
24
     question was not matching up with the actual wording
                                                          24
                                                                     ETH.MESH.02341213, was marked for
                                                          25
    in that third bullet point, I think.
                                                                     identification.)
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11 (Pages 330 to 333)

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Page 334
                                                                                                         Page 336
1
                                                            1
                                                                         MR. GAGE: I didn't know it was on
2
                                                            2
                                                                the exhibit.
     BY MR. BARLOW:
                                                            3
3
               Doctor, I'm going to hand you what
                                                                         MR. BARLOW: I can sit here and read
4
                                                            4
     I've marked as P-1657, and I'll represent to you
                                                                verbatim what's in front of me like a champ --
5
     that this is the TVT Abbrevo IFU in use from 9 --
                                                            5
                                                                actually, that's not true.
6
     September 10, 2010 until November 27th, 2014.
                                                            6
                                                                BY MR. BARLOW:
7
                                                            7
         A.
               That's correct.
                                                                          All right. I'm looking on this
                                                                    Q.
8
                                                            8
         O.
                                                                chart. I'm a little bit confused -- so maybe I
               Okay.
9
              Doctor, before we -- I question you
                                                            9
                                                                can't -- I'm looking at the Abbrevo IFUs and we've
10
     further on this, I'm looking at the -- do you have
                                                           10
                                                                got first use date and last use date.
                                                           11
11
     the chart?
                                                                         Now, the -- what I've -- the IFU that
12
                                                                I've just marked as 1657, the first use date is
              Have we marked this as an exhibit,
                                                           12
13
     the chart of the IFUs with dates? Is that an
                                                           13
                                                                September 10, 2010 and the last use date is listed
14
                                                           14
                                                                as 11/27/2014?
     exhibit yet?
15
              MS. KABBASH: I don't think it's been
                                                           15
                                                                          Yes.
                                                                    Α.
16
    marked.
                                                           16
                                                                    Q.
                                                                          And then if you go to the next IFU --
17
                                                           17
                                                                which I guess we'll go ahead and mark as P-1659.
              MR. BARLOW: Let's go ahead and do
18
     that. Do you have a chart that we can mark it?
                                                           18
19
              MR. GAGE: Yeah.
                                                           19
                                                                         (Deposition Exhibit No. P-1659,
                                                           20
20
              MR. BARLOW: If it's got your writing
                                                                      7/1/15-9/15/15 TVT Abbrevo IFU,
21
     on it, maybe we can get another copy.
                                                           21
                                                                      ETH.MESH.02617489 through
                                                                      ETH.MESH.02617499, was marked for
22
              THE WITNESS: I don't think it does.
                                                           22
              MR. GAGE: I don't think it does.
                                                           23
23
                                                                      identification.)
24
    Let me see. No. You've got an exhibit sticker?
                                                           24
              MR. BARLOW: Yeah. Let's mark the
25
                                                           25
                                                                         MR. BARLOW: I'll give you a copy of
                                                                                                         Page 337
1
     chart of IFUs for the various TVT family of products
                                                            1
                                                                it, Doctor.
2
     and the -- does this have the pelvic organ prolapse
                                                            2
                                                                BY MR. BARLOW:
3
                                                            3
                                                                    Q. It has a first use date of July 1st,
     products on it, too?
4
                                                                2015 and a last use date of September 15, 2015. Do
              MS. KABBASH: It does.
                                                            4
5
                                                            5
              MR. BARLOW: Okay -- and the pelvic
                                                                you see that?
6
     organ prolapse products that was produced to us by
                                                            6
                                                                    A.
                                                                          Yes.
7
     Ethicon and it's titled "Updated IFU Index and
                                                            7
                                                                          There appears to me to be a gap
8
                                                            8
     Production Bates Range Chart," and we're going to
                                                                between the Abbrevo -- one IFU to the next for the
9
                                                            9
                                                                Abbrevo. Do you know why that is?
     mark it as P-1658.
10
                                                           10
                                                                    A.
                                                                          I don't know specifically in this
                                                           11
11
              (Deposition Exhibit No. P-1658,
                                                                case.
12
           11/6/15 Updated IFU Index and Production
                                                           12
                                                                          Do you have an idea of what that
                                                                    Q.
                                                                might be?
                                                           13
13
           Bates Range Chart, was marked for
14
                                                           14
           identification.)
                                                                    A.
                                                                          Well, it -- the first use date is the
15
                                                           15
                                                                date of the beginning of the run of manufacturing
16
                                                           16
                                                                the device in which this was to be used. I don't
              MR. GAGE: And, Alex, for the record,
     can we identify the date, or the approximate date,
                                                           17
                                                                know whether there was a run between 11/27/14 and
17
                                                           18
     when this one was produced to plaintiffs?
                                                                7/1/15. They may have had enough product that they
18
                                                           19
19
              MR. BARLOW: This one was produced to
                                                                didn't do another run.
20
                                                           20
     plaintiffs on 11/6/15.
                                                                         I'm not sure of that. That's just
21
              MR. GAGE: Perfect. Thank you.
                                                           21
                                                                one possible explanation that I've seen in other
22
                                                           22
              MR. FREESE: Answer man.
                                                                cases.
              MR. BARLOW: I can read.
                                                           23
23
                                                                    Q.
                                                                          So, in other words, it could be that
24
              MR. FREESE: Shell answer man.
                                                           24
                                                                there was enough back stock, I guess, of the Abbrevo
              MR. BARLOW: That's right.
                                                           25
                                                                that already had the first IFU in the packaging, and
25
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12 (Pages 334 to 337)

Page 338 Page 340 1 a new IFU wasn't produced until you got through that indicated to be transitory; correct? 2 2 A. That's correct. stock. 3 3 In the current TVT Abbrevo IFU, it is Well, the new IFU may have been Q. A. 4 4 noted that the local -- there is no indication that produced, but it wasn't --5 5 Put into use. the local irritation is transitory; correct? Q. 6 6 The line -- yeah, the manufacture of MR. GAGE: Which one is the current? A. 7 the product in which it was going to be inserted --7 Is it 1659? 8 8 used didn't happen until 7/17/15, and that is a THE WITNESS: Is that 1659? 9 guess because I don't know for sure. 9 MR. BARLOW: Actually, current is 10 You don't know sitting here. 10 1656. Q. 11 Do you all know? 11 MR. GAGE: Oh, here it is. I'm MR. GAGE: Alex, counsel knows --12 12 sorry. 13 MS. KABBASH: He's actually correct. 13 MR. BARLOW: Strike that. I withdraw 14 So the reason why there's a gap is that the 14 the question. company's not making batches every day, so the IFU 15 15 MR. GAGE: Okay. will be approved for use. It will enter the bill of MR. BARLOW: Withdrawn. 16 16 17 materials, which is like a recipe for the batch. 17 BY MR. BARLOW: 18 The first use date will be day one 18 Doctor, the foreign body response 19 that the batch is made that that IFU is going into, 19 with regard to the TVT Abbrevo can be chronic, can't 20 and then the last use date is day one of the batch 20 it? 21 -- the last batch that that IFU goes into. 21 A. Histologically, yes. 22 So the next batch that's made might 22 Q. Chronic foreign body response is not be a couple months down the road because they just 23 in the TVT Abbrevo listed -- or listed in the 23 don't need to make another batch. So that explains 24 24 adverse reactions under the -- strike that. 25 25 Chronic foreign body response is not Page 339 Page 341 1 MR. BARLOW: Okay. I get it. I just 1 listed as an adverse reaction in 1657, the TVT 2 was confused. I wanted to make sure we weren't 2 Abbrevo IFU; correct? 3 3 It's not listed in those words. Its missing one. 4 actions are in the following section. 4 BY MR. BARLOW: 5 5 Doctor, the words chronic foreign All right, Doctor. Then let's talk 6 about the TVT Abbrevo IFU that I've marked as 6 body response do not appear in the actions section 7 P-1657, which was in use from September 10, 2010 7 either, do they? 8 until November 27th, 2014. Okay? No, they don't. 8 A. 9 9 In fact, the words chronic foreign A. O. Yes. 10 Q. Doctor, does the adverse reaction of 10 body response appear nowhere in the TVT Abbrevo IFU foreign body response resulting in inflammation, 11 which has been marked as Exhibit 1657; correct? 11 extrusion, erosion, exposure, and fistula formation 12 12 Α. That's correct. 13 13 appear in that IFU? Q. Doctor, does the adverse reaction 14 14 mesh extrusion, exposure, or erosion into the vagina A. Yes. 15 Q. Where? 15 or other structures or organs appear in the adverse 16 Adverse reactions, second bullet, 16 reactions section of the TVT Abbrevo which has been A. transitory local irritation at the wound site and 17 marked as Exhibit 16 -- IFU which has been marked as 17 transitory foreign body response may occur. This 18 Exhibit 1657? 18 response could result in extrusion, erosion, fistula 19 The vagina and other organs is not 19 A. 20 formation, or inflammation. 20 spelled out. Doctor, in the IFU for the Abbrevo, 21 21 Doctor, in the adverse reactions 22 which is marked as 1657, the local irritation is 22 section of the Abbrevo IFU, which has been marked as listed as -- or noted to be transitory; correct? 23 Exhibit 1657, acute and/or chronic pain does not 23 appear; correct? 24 A. That's correct. 24 25 25 Correct. Q. And the foreign body response is A.

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Page 342 Page 344 1 In fact, acute and/or chronic pain 1 A. That's correct. 2 does not appear anywhere in the TVT Abbrevo IFU that 2 Q. And the IFU which has been marked as 3 has been marked as Exhibit 1657; correct? 3 Exhibit 1657 does not note chronic thigh and leg 4 1657 -- wait a minute. Let me make 4 pain can result from the TVT Abbrevo, does it? 5 5 sure I'm on the right one. No. it doesn't. A. This is the -- the IFU that was in б And, Doctor, acute and/or chronic 6 O. 7 use from September 2010 to November 2014. 7 pain in the pelvis and/or abdominal area -- pelvic 8 8 Yeah, can you ask that question and/or abdominal area is not listed in the TVT 9 again, please? 9 Abbrevo IFU which has been marked as Exhibit 1657; 10 Q. 10 correct? Sure. Or have that read back? 11 11 A. Correct. A. Doctor, the TVT Abbrevo IFU which has 12 O. Sure. Acute and/or chronic pain does 12 Q. 13 not appear in the TVT Abbrevo IFU that is marked as 13 been marked as 1657 does not list -- strike that. 14 Exhibit 1657, does it? 14 The TVT Abbrevo IFU which has been 15 A. Well, it discusses transient leg pain 15 marked as Exhibit 1657 does not discuss that adverse in the warnings and precautions. 16 16 reactions may require surgical treatment, does it? 17 Doctor, that transient leg pain does 17 A. No. not encompass all of the acute and/or chronic pain 18 Q. Doctor, the IFU which has been marked 18 that can result from use of the TVT Abbrevo; 19 19 as Exhibit 1657 for the Abbrevo does not list that 20 20 correct? one or more revision surgeries may be necessary to 21 A. No, it doesn't. 21 treat the adverse reactions that can result from the 22 Q. And chronic pain appears nowhere in 22 Abbrevo, does it? 23 the TVT Abbrevo IFU which has been marked as Exhibit 23 A. No. 24 Doctor, the TVT -- TVT Abbrevo IFU 24 1657, does it? Q. 25 25 which has been marked as Exhibit 1657 does not A. That's correct. Page 345 Page 343 1 And other than transitory leg pain, 1 discuss that in cases in which Prolene mesh needs to 2 acute pain does not occur -- does not appear in the 2 be removed in part or whole, significant dissection 3 TVT Abbrevo IFU, which has been marked as Exhibit 3 may be required, does it? 1657; correct? 4 No. 4 A. 5 5 A. The word acute does not. And, Doctor, the TVT Abbrevo IFU 6 Q. Doctor, is pain with intercourse, 6 which has been marked as Exhibit 1657 does not state 7 which in some patients may not resolve, included in 7 anywhere in it that even when revision surgeries are the adverse reactions listed in the TVT Abbrevo IFU 8 8 performed to treat adverse reactions, that those 9 9 which has been marked as Exhibit 1657? adverse reactions may not resolve; correct? 10 Α. 10 A. Correct. 11 11 Doctor, in the TVT Abbrevo IFU, which O. Doctor, do neuromuscular problems, O. 12 including acute and/or chronic pain in the groin, 12 has been marked as Exhibit 1657, does it warn that thigh, leg, pelvic or abdominal area appear in the 13 13 de novo urge incontinence can result from the 14 adverse reactions listed in the TVT Abbrevo IFU 14 Abbrevo's use? 15 15 which has been marked as 1657? A. 16 No, but leg pain does occur in the 16 O. Doctor, in the TVT Abbrevo IFU that A. 17 warnings and precautions section. 17 is marked as Exhibit 1657, does it warn that de novo Neuromuscular problems is not listed 18 18 urinary frequency can result from its use? in the adverse reactions section of the TVT Abbrevo 19 19 A. No. 20 IFU, which has been marked as Exhibit 1657; correct? 20 Doctor, in the TVT Abbrevo IFU which 21 A. Correct. 21 has been marked as Exhibit 1657, does it warn that 22 22 Q. And acute and/or chronic pain in the de novo urinary retention can result from its use? groin does not appear listed in the adverse 23 Only in reference to lower urinary 23 A. 24 reactions that can occur with the TVT Abbrevo; 24 tract obstruction. 25 25 correct? And, Doctor, there are other lower --

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1 A. That's correct. However, it doesn't 2 say by the surgeon. It just says over-tensioning or 3 overcorrection. 4 MR. BARLOW: Move to strike as 4 reaction; correct? 5 nonresponsive. 6 THE WITNESS: Okay. 7 BY MR. BARLOW: 8 Q. Doctor, it says, too much tension 9 applied to the mesh implant. Right? 10 A. Yes. 11 Q. That suggests surgeon error; correct? 12 A. Or swelling. 13 Q. Doctor, urinary obstruction can occur 14 with the TVT Abbrevo from scarification; correct? 15 A. It could. 16 Q. Obstruction resulting from 17 scarification with regard to the TVT Abbrevo is not listed as an adverse reaction in the IFU which is 18 marked as Exhibit 1657; correct? 19 A. Correct. Q. And, Doctor, you would agree with me 10 A. Yes. 11 Chronic foreign body response resulting in extrusion is not listed in the TVT Abbrevo is not listed in the TVT Abbrevo IFU that is 17 extrusion strike that. 18 Chronic foreign body response resulting in extrusion is not listed in the Abbrevo IFU that has been marked as Exhibit 1659, does it? A. No. 16 Q. And, Doctor, you would agree with me 17 that swelling does not appear anywhere in the TVT 18 A. No. 20 And, Correct? 21 Q. And, Doctor, you would agree with me 22 that swelling does not appear anywhere in the TVT 23 Abbrevo IFU; correct? 24 A. No. 25 MR. GAGE: Let me ask you a question. 26 MR. GAGE: Let me ask you a question.		Page 346		Page 348
A. It can be. Q. Can be. Okay. The TVT Abbrevo IFU that's been marked as Exhibit 1657 does not explicitly list urinary retention as a possibility, correct? A. That's correct, not in those words. Q. Okay. Where does it point me to that. A. It's the last adverse reaction. Q. Doctor, the Obstruction and score with the in the adverse reaction in the adverse reaction and the revision ing during implant; correct? A. That's correct. A. That's correct. A. Possibly, yes. Q. And that possibility is not listed in the TVT Abbrevo when there is not over-tensioning by the surgeon; correct? A. Possibly, yes. Q. And that possibility is not listed in the TVT Abbrevo is not interpreted in the mesh implant. Right? A. That's correct. However, it doesn't say by the surgeon. It just says over-tensioning or oper-correction. A. Yes. Q. Doctor, it says, too much tension applied to the mesh implant. Right? A. Yes. Q. Doctor, it says, too much tension applied to the mesh implant. Right? A. Yes. Q. Doctor, it says, too much tension applied to the mesh implant. Right? A. Yes. Q. Doctor, it says, too much tension applied to the mesh implant. Right? A. Yes. Q. Doctor, it says, too much tension applied to the mesh implant. Right? A. Yes. Q. Doctor, it says too much tension applied to the mesh implant. Right? A. Yes. Q. Doctor, it says, too much tension applied to the mesh implant. Right? A. Yes. Q. Doctor, it says too much tension applied to the mesh implant. Right? A. Yes. Q. Doctor, it says, too much tension applied to the mesh implant. Right? A. Yes. Q. Doctor, it says too much tension applied to the mesh implant. Right? A. Yes. Q. Doctor, it says too much tension applied to the mesh implant. Right? A. Yes. Q. Doctor, chronic foreign body response resulting in inflammation that is not transitory, it is not listed in the TVT Abbrevo IFU that is marked as Exhibit 1657; correct? A. It could. Q. And, Doctor, you would agree with me that swelling does not appear anywhere in the TVT Abbrevo iBCQ. Let me ask you a question. If the two face o	1	well, urinary retention is a result of obstruction.	1	regards to over-tensioning; correct?
4	2	Right?	2	A. That's correct.
The TVT Abbrevo FU that's been marked as Exhibit 1657 does not explicitly list urinary retention as a possibility; correct? A. That's correct, not in those words. A. That's correct, not in those words. A. Yes. Q. Okay. 11 A. Yes. Q. Octor, the obstruction that is noted in the adverse reactions flow diverse reactions is to obstruction resulting from over-tensioning during implant; correct? A. That's correct. A. That's correct. A. Possibly, yes. Q. Obstruction can also occur with the TVT Abbrevo when there is not over-tensioning by the surgeon. It just says over-tensioning or over-correction. A. That's correct. However, it doesn't asy by the surgeon. It just says over-tensioning or over-correction. A. That's correct. However, it doesn't asy by the surgeon. It just says over-tensioning or opinite to the mesh implant. Right? A. Yes. Q. Doctor, chronic foreign body response reaction; correct? A. Yes. Q. Doctor, chronic foreign body response resulting in inflammation that is not transitory, it's not listed in the action; correct? A. Yes. Q. Doctor, chronic foreign body response resulting in inflammation that is not transitory, it's not listed as a adverse reaction in the FU which is listed as an adverse reaction in the first win the action; correct? A. Yes. Q. Doctor, chronic foreign body response resulting in inflammation that is not transitory, it's not listed in the TVT Abbrevo IFU that is marked as Exhibit 1657; correct? A. Yes. Q. Doctor, chronic foreign body response resulting in inflammation that is not transitory, it's not listed in the TVT Abbrevo IFU that is marked as Exhibit 1657; correct? A. Yes. Q. Doctor, chronic foreign body response resulting in inflammation that is not transitory, it's not listed in the TVT Abbrevo IFU that is marked as Exhibit 1657; correct? A. Yes. Q. Doctor, chronic foreign body response resulting in inflammation that is not transitory, it's not listed in the TVT Abbrevo IFU that is marked as Exhibit 1659, does it'. A. Yes. Q. Doctor, chronic foreign bo	3		3	Q. Doctor, the TVT Abbrevo IFU that's
The TVT Abbrevo FU that's been marked as Exhibit 1657 does not explicitly list urinary retention as a possibility; correct? 8 A. That's correct, not in those words. 8 A. That's correct; 9 Q. It does discuss that de novo 10 obstruction can occur; correct? 11 A. Yes. 12 Q. Okay. 13 Where does it point me to that. 14 A. It's the last adverse reaction. 15 Q. Doctor, the obstruction that is noted in the adverse reaction is list obstruction resulting from over-tensioning during implant; correct? 16 TVT Abbrevo when there is not over-tensioning by the surgeon. It just says over-tensioning or over-correction. 17 A. That's correct. However, it doesn't a yaby the surgeon. It just says over-tensioning or over-orrection. 18 A. That's correct. However, it doesn't a pay by the surgeon. It just says over-tensioning or over-orrection. 2 A. Yes. 2 A. Ossiblity es. 3 Q. Okay. 3 Q. It does discuss that de novo obstruction. 4 A. That's correct. 4 The TVT Abbrevo is not spear anywhere in the TVT Abbrevo is not spear anywhere in the TVT Abbrevo is not listed as an adverse reaction in the TVT Abbrevo is not scriffication with regard to the TVT Abbrevo is not listed as an adverse reaction in the TVT Abbrevo is not listed as an adverse reaction in the TVT Abbrevo is not listed as an adverse reaction in the TVT Abbrevo is not listed as an adverse reaction in the TVT Abbrevo is not listed as an adverse reaction in the TVT Abbrevo is not listed as an adverse reaction in the TVT Abbrevo is not listed as an adverse reaction in the TVT Abbrevo is not listed as an adverse reaction in the TVT Abbrevo is not listed as an adverse reaction in the TVT Abbrevo is not listed as an adverse reaction in the TVT Abbrevo is not listed as Exhibit 1657; correct? 10 Q. Doctor, the obstruction that is not transitory, it is not listed in the Abbrevo is not listed in the TVT Abbrevo is not listed in the TVT Abbrevo is not listed as an adverse reaction in the It FU which is listed as an adverse reaction in the It FU which is listed as an adverse reaction i	4	Q. Can be. Okay.	4	marked as Exhibit 1657 does not warn about the
form the Abbrevo, does it? A. That's correct, not in those words. 8 New Years of the TVT Abbrevo IFU that's marked as Exhibit 1659, which I believe is the TVT Abbrevo IFU that's marked as Exhibit 1659, and I'm referring in that instance to the IFU marked as Exhibit 1659, and I'm referring in that instance to the IFU marked as Exhibit 1659, and I'm referring in that instance to the IFU marked as Exhibit 1659, and I'm referring in that instance to the IFU marked as Exhibit 1659, and I'm referring in that instance to the IFU marked as Exhibit 1659, and I'm referring in that instance to the IFU marked as Exhibit 1659, and I'm starked as Exhibit 1659, and I'm referring in that instance to the IFU marked as Exhibit 1659, and I'm referring in that instance to the IFU marked as Exhibit 1659, and I'm referring in that instance to the IFU marked as Exhibit 1659, and I'm referring in that instance to the IFU marked as Exhibit 1659, and I'm referring in that instance to the IFU marked as Exhibit 1659, and I'm referring in that instance to the IFU marked as Exhibit 1659, and I'm referring in that instance to the IFU marked as Exhibit 1659, and I'm referring in that instance to the IFU marked as Exhibit 1659, and I'm referring in that instance to the IFU marked as Exhibit 1659, and I'm referring in that instance to the IFU marked as Exhibit 1659, and I'm referring in that instance to the IFU marked as Exhibit 1659, and I'm referring in that instance to the IFU marked as Exhibit 1659, and I'm referring in that instance to the IFU marked as Exhibit 1659, and I'm referring in that instance to the IFU marked as Exhibit 1659, and I'm referring in that instance to the IFU marked as Exhibit 1659, and I'm referring in that instance to	5		5	possibility of de novo voiding dysfunction resulting
rimary retention as a possibility; correct? A That's correct, not in those words. Q It does discuss that de novo Q It does discuss that de novo Q It does discuss that de novo Q There are other types of voiding dysfunction; correct? A Yes. Q Okay. A It's the last adverse reaction. Q Doctor, the obstruction resulting in the adverse reactions list obstruction resulting from over-tensioning during implant; correct? A That's correct. Q Obstruction can also occur with the surgeon; correct? A Possibly, yes. Page 347 A That's correct. However, it doesn't say by the surgeon. It just says over-tensioning or over-correction. MR. BARLOW: Move to strike as nonresponsive. A The With ETVT Abbrevo from scarification; correct? A Or swelling. Q Doctor, the obstruction can also occur with the the TVT Abbrevo is not with the the tyth abbrevo is not its din the TVT Abbrevo is not with regard to the TVT Abbrevo from scarification with regard to the TVT Abbrevo is not its listed as an adverse reaction in the FIV which is listed as an adverse reaction in the FIV which is listed as an adverse reaction in the FIV which is listed as an adverse reaction in the FIV which is listed as an adverse reaction in the FIV which is listed as an adverse reaction in the FIV which is listed as an adverse reaction in the FIV which is listed as an adverse reaction in the FIV which is listed as an adverse reaction in the FIV which is listed as an adverse reaction in the FIV which is listed as an adverse reaction in the FIV which is listed as an adverse reaction in the FIV which is listed as an adverse reaction in the FIV which is listed as an adverse reaction in the FIV which is listed as an adverse reaction in the FIV which is listed as an adverse reaction in the FIV which is listed as an adverse reaction in the FIV which is listed as an adverse reaction in the FIV which is listed as an adverse reaction in the FIV which is listed as an adverse reaction in the FIV which is listed as an adverse reaction in the FIV which is listed as an a	6	marked as Exhibit 1657 does not explicitly list	6	
A. That's correct, not in those words. Q. It does discuss that de novo obstruction can occur; correct? 11 A. Yes. 11 A. Yes. 11 Q. Okay. 12 Q. Okay. 13 Where does it point me to that. 14 A. It's the last adverse reaction. 15 Q. Doctor, the obstruction that is noted 16 in the adverse reactions list obstruction resulting 17 from over-tensioning during implant; correct? 18 A. That's correct. 19 Q. Obstruction can also occur with the 19 Q. Obstruction can also occur with the 20 TVT Abbrevo when there is not over-tensioning by the 21 surgeon; correct? 22 A. Possibly, yes. 23 Q. And that possibility is not listed in 24 the TVT Abbrevo IPU that's marked as Exhibit 1657; 25 correct? 26 A. That's correct. However, it doesn't 27 say by the surgeon. It just says over-tensioning or over-correction. 28 Q. Doctor, chronic foreign body response 29 applied to the mesh implant. Right? 29 Q. Doctor, it says, too much tension 29 applied to the mesh implant. Right? 20 Q. Doctor, it says, too much tension 21 public to the mesh implant. Right? 22 A. Yes. 23 Q. Doctor, chronic foreign body response 24 c. Yes. 25 (Q. Doctor, chronic foreign body response reaction; correct? 26 A. Yes. 27 A. Yes. 28 Q. Doctor, chronic foreign body response 29 applied to the mesh implant. Right? 30 Q. Doctor, urinary obstruction can occur with the TVT Abbrevo irruction. 31 correct. 32 A. Yes. 33 Q. Doctor, urinary obstruction can occur with the TVT Abbrevo irruction can occur with the TVT Abbrevo from scarification; correct? 4 A. Yes. 4 Q. Doctor, foreign body response resulting in marked as Exhibit 1659, does it? 4 A. Yes. 4 Q. Doctor, foreign body response resulting in extrusion strike that. 4 With the TVT Abbrevo from scarification; correct? 4 A. Yes. 4 Q. Doctor, foreign body response resulting in extrusion is not listed in the TVT Abbrevo lift that is not transitory, it's not listed in the TVT Abbrevo lift that is not transitory, it's not listed in the TVT Abbrevo lift that is not transitory, it's not listed in the TVT Abbrevo lift that is no	7		7	A. Only in the when it refers to
bostruction can occur; correct? A. Yes. Okay. It's the last adverse reaction. It's the last adverse reaction. Doctor, the obstruction resulting in the adverse reactions list obstruction resulting also occur with the TVT Abbrevo's used, yes. To TVT Abbrevo when there is not over-tensioning by the surgeon; correct? A. Possibly, yes. A. Possibly, yes. A. Possibly, yes. A. A. That's correct. However, it doesn't say by the surgeon. It just says over-tensioning or over-correction. A. That's correct. However, it doesn't say by the surgeon. It just says over-tensioning or over-correction. A. That's correct. However, it doesn't say by the surgeon. It just says over-tensioning or over-correction. A. That's correct. However, it doesn't say by the surgeon. It just says over-tensioning or over-correction. A. That's correct. However, it doesn't say by the surgeon. It just says over-tensioning or oper-correction. A. That's correct. However, it doesn't say by the surgeon. It just says over-tensioning or oper-correction. A. That's correct. However, it doesn't say by the surgeon. It just says over-tensioning or oper-correction. A. That's correct. However, it doesn't say by the surgeon. It just says over-tensioning or oper-correction. A. That's correct. However, it doesn't say by the surgeon. It just says over-tensioning or oper-correction. A. That's correct. However, it doesn't say by the surgeon. It just says over-tensioning or oper-correction. A. That's correct however, it doesn't say by the surgeon error; correct? A. Yes. Doctor, chronic foreign body response reaction; correct? A. Yes. Q. Doctor, it says, too much tension applead to the mesh implant. Right? A. Yes. Q. Doctor, it says, too much tension applead to the mesh implant. Bight? A. It could. Q. Doctor, urinary obstruction can occur with the TVT Abbrevo from scarification; correct? A. Yes. Q. Doctor, it says, too much tension applead to the mesh implant. Bight? A. It could. Q. Doctor, urinary obstruction can occur with the TVT Abbrevo fr	8		8	*
dysfunction; correct? 10 dysfunction; correct? 11 A. Yes. 20 Okay. 12 Q. There are other types of voiding dysfunction that can result from the TVT Abbrevo; correct? 13 A. Tes. Correct? A. From the procedure in which the TVT Abbrevo's used, yes. Q. There are other types of voiding dysfunction that can result from the TVT Abbrevo's used, yes. Q. There are other types of voiding dysfunction that can result from the TVT Abbrevo's used, yes. Q. There are other types of voiding dysfunction that can result from the trVT Abbrevo's used, yes. Q. There are other types of voiding dysfunction that can result from the use of the TVT Abbrevo's used, yes. Q. There are other types of voiding dysfunction that can result from the use of the TVT Abbrevo's used, yes. Q. There are other types of voiding dysfunction that can result from the use of the TVT Abbrevo's used, yes. Q. There are other types of voiding dysfunction that can result from the Use of the TVT Abbrevo's used, yes. Q. Doctor, the obstruction can also occur with the types of voiding dysfunction that can result from the TVT Abbrevo's used, yes. Q. Doctor, the obstruction can also occur with the types of voiding dysfunction that can result from the TVT Abbrevo's used, yes. Q. Doctor, the obstruction got over orderet? A. Yes. Q. Doctor, test sum to Exhibit 1659, A. Yes. Q. Doctor, the obstruction as September Doctor, the obstruction as September Septe	9		9	*
11 A. Yes. Q. Okay. Where does it point me to that. A. It's the last adverse reaction. Operation that can result from the TVT Abbrevo; correct? In the adverse reactions list obstruction resulting from over-tensioning during implant; correct? Operation that can result from the TVT Abbrevo; correct? A. That's correct. Operation that can result from the TVT Abbrevo; correct? A. That's correct. Operation that can result from the TVT Abbrevo; correct? A. That's correct. Operation that can result from the TVT Abbrevo; correct? A. That's correct. Operation that can result from the TVT Abbrevo; correct? A. That's correct. Operation that can result from the TVT Abbrevo; correct? A. That's correct. Operation that can result from the TVT Abbrevo; correct? A. That's correct. Operation that can result from the TVT Abbrevo; correct? A. That's correct. Operation that can result from the TVT Abbrevo; correct? A. That's correct. Operation that can result from the TVT Abbrevo; correct? A. That's correct. Operation that can result from the TVT Abbrevo; correct? A. That's correct. Operation that can result from the TVT Abbrevo; correct? A. Yes. Operation that can result from the TVT Abbrevo; correct? Abbrevo's used, yes. Operation that can result from the TVT Abbrevo; correct? A. Yes. Operation that can result from the TVT Abbrevo; correct? A. Yes. Operation that can result from the TVT Abbrevo; correct? Abbrevo's used, yes. Operation that can result from the TVT Abbrevo; correct? A. Yes. Operation that can result from the TVT Abbrevo; correct? A. Yes. Operation that can result from the TVT Abbrevo; correct? A. Yes. Operation that can result from the TVT Abbrevo; correct? A. Yes. Operation that can result from the TVT Abbrevo; correct? A. Yes. Operation that can result from the TVT Abbrevo; correct? A. Yes. Operation that can result from the TVT Abbrevo; correct? A. Yes. Operation that can result from the TVT Abbrevo; correct? A. Yes. Operation that can result from the TVT Abbrevo; correct? A. Yes. Operation that can result fro	10	obstruction can occur; correct?	10	
13	11	A. Yes.	11	
Where does it point me to that. 14	12	Q. Okay.	12	Q. There are other types of voiding
A. It's the last adverse reaction. Q. Doctor, the obstruction that is noted in the adverse reactions list obstruction resulting from over-tensioning during implant; correct? A. That's correct. Q. Obstruction can also occur with the TVT Abbrevo when there is not over-tensioning by the surgeon; correct? A. Possibly, yes. Q. And that possibility is not listed in the TVT Abbrevo IFU that's marked as Exhibit 1657; correct? Page 347 A. That's correct. However, it doesn't say by the surgeon. It just says over-tensioning or overcorrection. MR. BARLOW: Move to strike as nonresponsive. MR. BARLOW: Move to strike as nonresponsive. THE WITNESS: Okay. BY MR. BARLOW: Q. Doctor, it says, too much tension applied to the mesh implant. Right? A. Yes. Q. Doctor, it says, too much tension applied to the mesh implant. Right? A. Yes. Q. Doctor, it says, too much tension applied to the mesh implant. Right? A. Yes. Q. Doctor, urinary obstruction can occur with the TVT Abbrevo irrect? A. It could. Q. Obstruction can also occur with the TVT Abbrevo is not listed as an adverse reaction in the IFU which is marked as Exhibit 1657; correct? A. Correct. A. Correct. A. Correct. A. It could. Q. Obstruction resulting from scarification with regard to the TVT Abbrevo is not listed as an adverse reaction in the IFU which is marked as Exhibit 1657; correct? A. Correct. Q. And, Doctor, you would agree with me tas welling does not appear anywhere in the TVT Abbrevo if IFU that has been marked as Exhibit 1659, does it? A. No. MR. GAGE: Let me ask you a question.	13		13	
Doctor, the obstruction that is noted in the adverse reactions list obstruction resulting from over-tensioning during implant; correct? A. That's correct. Q. Obstruction can also occur with the TVT Abbrevo when there is not over-tensioning by the surgeon; correct? A. Possibly, yes. Q. And that possibility is not listed in the TVT Abbrevo is provered. A. That's correct. However, it doesn't say by the surgeon. It just says over-tensioning or overcorrection. A. That's correct. However, it doesn't say by the surgeon. It just says over-tensioning or overcorrection. A. That's correct. However, it doesn't say by the surgeon. It just says over-tensioning or overcorrection. A. That's correct. However, it doesn't say by the surgeon. It just says over-tensioning or overcorrection. A. That's correct. However, it doesn't say by the surgeon. It just says over-tensioning or overcorrection. A. That's correct. However, it doesn't say by the surgeon. It just says over-tensioning or overcorrection. BY MR. BARLOW: Move to strike as nonresponsive. THE WITNESS: Okay. BY MR. BARLOW: D. Doctor, it says, too much tension applied to the mesh implant. Right? A. Yes. Q. Doctor, it says, too much tension applied to the mesh implant. Right? A. Yes. Q. Doctor, it says, too much tension applied to the mesh implant. Right? A. Yes. Q. Doctor, it says, too much tension applied to the mesh implant. Right? A. Yes. Q. Doctor, it says, too much tension applied to the mesh implant. Right? A. Yes. Q. Doctor, it says, too much tension applied to the mesh implant of the mesh implant. Right? A. Yes. Q. Doctor, it says, too by the surgeon error; correct? A. It could. Q. Dostor, the abbrevo is to the IVT	14		14	
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9 applied to the mesh implant. Right? 10 A. Yes. 11 Q. That suggests surgeon error; correct? 12 A. Or swelling. 13 Q. Doctor, urinary obstruction can occur 14 with the TVT Abbrevo from scarification; correct? 15 A. It could. 16 Q. Obstruction resulting from 17 scarification with regard to the TVT Abbrevo is not listed as an adverse reaction in the IFU which is 18 listed as an adverse reaction in the IFU which is 19 marked as Exhibit 1657; correct? 20 A. Correct. 21 Q. And, Doctor, you would agree with me 22 that swelling does not appear anywhere in the TVT 23 Abbrevo IFU; correct? 24 Q. Abbrevo IFU; correct? 25 Abbrevo IFU; correct? 26 Abbrevo IFU; correct? 27 Abbrevo IFU; correct? 28 Abbrevo IFU; correct? 39 Q. Do you understand that? 40 A. Yes. 41 Q. Doctor, foreign body response 42 resulting in inflammation that is not transitory, 43 it's not listed in the TVT Abbrevo IFU that is 44 marked as Exhibit 1659, is it? 45 A. No. 46 Q. Foreign body response resulting in 47 extrusion strike that. 48 Chronic foreign body response 49 resulting in extrusion is not listed in the Abbrevo 40 IFU that has been marked as Exhibit 1659, does it? 40 A. Yes. 41 Q. Doctor, foreign body response resulting in extrusion strike that. 49 resulting in extrusion is not listed in the Abbrevo 40 IFU that has been marked as Exhibit 1659, does it? 41 A. No. 42 MR. GAGE: Let me ask you a question. 43 Is 1659 can I just compare quickly? Just a	2 3 4 5	A. That's correct. However, it doesn't say by the surgeon. It just says over-tensioning or overcorrection. MR. BARLOW: Move to strike as nonresponsive.	2 3 4 5	A. Yes. Q. Doctor, chronic foreign body response is not listed in the TVT Abbrevo IFU as an adverse reaction; correct? A. Correct.
10 A. Yes. 11 Q. That suggests surgeon error; correct? 12 A. Or swelling. 13 Q. Doctor, urinary obstruction can occur 14 with the TVT Abbrevo from scarification; correct? 15 A. It could. 16 Q. Obstruction resulting from 17 scarification with regard to the TVT Abbrevo is not 18 listed as an adverse reaction in the IFU which is 19 marked as Exhibit 1657; correct? 20 A. Correct. 21 Q. Doctor, foreign body response 12 resulting in inflammation that is not transitory, 13 it's not listed in the TVT Abbrevo IFU that is 14 marked as Exhibit 1659, is it? 15 A. No. 16 Q. Foreign body response resulting in 17 extrusion strike that. 18 Chronic foreign body response 19 resulting in extrusion is not listed in the Abbrevo 20 IFU that has been marked as Exhibit 1659, does it? 21 Q. And, Doctor, you would agree with me 22 that swelling does not appear anywhere in the TVT 23 Abbrevo IFU; correct? 20 MR. GAGE: Let me ask you a question. 23 Is 1659 can I just compare quickly? Just a	2 3 4 5 6	A. That's correct. However, it doesn't say by the surgeon. It just says over-tensioning or overcorrection. MR. BARLOW: Move to strike as nonresponsive. THE WITNESS: Okay.	2 3 4 5 6	A. Yes. Q. Doctor, chronic foreign body response is not listed in the TVT Abbrevo IFU as an adverse reaction; correct? A. Correct. Q. And I'm referring in that instance to
10 A. Yes. 11 Q. That suggests surgeon error; correct? 12 A. Or swelling. 13 Q. Doctor, urinary obstruction can occur 14 with the TVT Abbrevo from scarification; correct? 15 A. It could. 16 Q. Obstruction resulting from 17 scarification with regard to the TVT Abbrevo is not 18 listed as an adverse reaction in the IFU which is 19 marked as Exhibit 1657; correct? 20 A. Correct. 21 Q. And, Doctor, you would agree with me 22 that swelling does not appear anywhere in the TVT 23 Abbrevo IFU; correct? 20 Abbrevo IFU; correct? 21 Q. Abbrevo IFU; correct? 22 MR. GAGE: Let me ask you a question. 23 Is 1659 can I just compare quickly? Just a	2 3 4 5 6 7	A. That's correct. However, it doesn't say by the surgeon. It just says over-tensioning or overcorrection. MR. BARLOW: Move to strike as nonresponsive. THE WITNESS: Okay. BY MR. BARLOW:	2 3 4 5 6 7	A. Yes. Q. Doctor, chronic foreign body response is not listed in the TVT Abbrevo IFU as an adverse reaction; correct? A. Correct. Q. And I'm referring in that instance to the IFU marked as Exhibit 1659.
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 with the TVT Abbrevo from scarification; correct? A. It could. Q. Obstruction resulting from scarification with regard to the TVT Abbrevo is not listed as an adverse reaction in the IFU which is marked as Exhibit 1659, is it? Q. Foreign body response resulting in extrusion strike that. Chronic foreign body response resulting in extrusion is not listed in the Abbrevo Q. And, Doctor, you would agree with me that swelling does not appear anywhere in the TVT Abbrevo IFU; correct? MR. GAGE: Let me ask you a question. Is 1659 can I just compare quickly? Just a 	2 3 4 5 6 7 8 9	A. That's correct. However, it doesn't say by the surgeon. It just says over-tensioning or overcorrection. MR. BARLOW: Move to strike as nonresponsive. THE WITNESS: Okay. BY MR. BARLOW: Q. Doctor, it says, too much tension applied to the mesh implant. Right? A. Yes.	2 3 4 5 6 7 8 9	A. Yes. Q. Doctor, chronic foreign body response is not listed in the TVT Abbrevo IFU as an adverse reaction; correct? A. Correct. Q. And I'm referring in that instance to the IFU marked as Exhibit 1659. A. Yes. Q. Do you understand that? A. Yes.
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Q. Obstruction resulting from scarification with regard to the TVT Abbrevo is not listed as an adverse reaction in the IFU which is marked as Exhibit 1657; correct? A. Correct. Q. And, Doctor, you would agree with me that swelling does not appear anywhere in the TVT Abbrevo IFU; correct? 16 Q. Foreign body response resulting in extrusion strike that. 18 Chronic foreign body response resulting in extrusion is not listed in the Abbrevo IFU that has been marked as Exhibit 1659, does it? A. No. MR. GAGE: Let me ask you a question. 23 Is 1659 can I just compare quickly? Just a	2 3 4 5 6 7 8 9 10 11 12	A. That's correct. However, it doesn't say by the surgeon. It just says over-tensioning or overcorrection. MR. BARLOW: Move to strike as nonresponsive. THE WITNESS: Okay. BY MR. BARLOW: Q. Doctor, it says, too much tension applied to the mesh implant. Right? A. Yes. Q. That suggests surgeon error; correct? A. Or swelling.	2 3 4 5 6 7 8 9 10 11 12	A. Yes. Q. Doctor, chronic foreign body response is not listed in the TVT Abbrevo IFU as an adverse reaction; correct? A. Correct. Q. And I'm referring in that instance to the IFU marked as Exhibit 1659. A. Yes. Q. Do you understand that? A. Yes. Q. Doctor, foreign body response resulting in inflammation that is not transitory,
17 scarification with regard to the TVT Abbrevo is not 18 listed as an adverse reaction in the IFU which is 19 marked as Exhibit 1657; correct? 20 A. Correct. 21 Q. And, Doctor, you would agree with me 22 that swelling does not appear anywhere in the TVT 23 Abbrevo IFU; correct? 17 extrusion strike that. 18 Chronic foreign body response resulting in extrusion is not listed in the Abbrevo 20 IFU that has been marked as Exhibit 1659, does it? 21 A. No. 22 MR. GAGE: Let me ask you a question. 23 Is 1659 can I just compare quickly? Just a	2 3 4 5 6 7 8 9 10 11 12 13 14	A. That's correct. However, it doesn't say by the surgeon. It just says over-tensioning or overcorrection. MR. BARLOW: Move to strike as nonresponsive. THE WITNESS: Okay. BY MR. BARLOW: Q. Doctor, it says, too much tension applied to the mesh implant. Right? A. Yes. Q. That suggests surgeon error; correct? A. Or swelling. Q. Doctor, urinary obstruction can occur	2 3 4 5 6 7 8 9 10 11 12 13	A. Yes. Q. Doctor, chronic foreign body response is not listed in the TVT Abbrevo IFU as an adverse reaction; correct? A. Correct. Q. And I'm referring in that instance to the IFU marked as Exhibit 1659. A. Yes. Q. Do you understand that? A. Yes. Q. Doctor, foreign body response resulting in inflammation that is not transitory, it's not listed in the TVT Abbrevo IFU that is
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23 Abbrevo IFU; correct? 23 Is 1659 can I just compare quickly? Just a	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	A. That's correct. However, it doesn't say by the surgeon. It just says over-tensioning or overcorrection. MR. BARLOW: Move to strike as nonresponsive. THE WITNESS: Okay. BY MR. BARLOW: Q. Doctor, it says, too much tension applied to the mesh implant. Right? A. Yes. Q. That suggests surgeon error; correct? A. Or swelling. Q. Doctor, urinary obstruction can occur with the TVT Abbrevo from scarification; correct? A. It could. Q. Obstruction resulting from scarification with regard to the TVT Abbrevo is not listed as an adverse reaction in the IFU which is marked as Exhibit 1657; correct? A. Correct.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. Yes. Q. Doctor, chronic foreign body response is not listed in the TVT Abbrevo IFU as an adverse reaction; correct? A. Correct. Q. And I'm referring in that instance to the IFU marked as Exhibit 1659. A. Yes. Q. Do you understand that? A. Yes. Q. Doctor, foreign body response resulting in inflammation that is not transitory, it's not listed in the TVT Abbrevo IFU that is marked as Exhibit 1659, is it? A. No. Q. Foreign body response resulting in extrusion strike that. Chronic foreign body response resulting in extrusion is not listed in the Abbrevo IFU that has been marked as Exhibit 1659, does it?
24 A That word does not occur 24 second	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. That's correct. However, it doesn't say by the surgeon. It just says over-tensioning or overcorrection. MR. BARLOW: Move to strike as nonresponsive. THE WITNESS: Okay. BY MR. BARLOW: Q. Doctor, it says, too much tension applied to the mesh implant. Right? A. Yes. Q. That suggests surgeon error; correct? A. Or swelling. Q. Doctor, urinary obstruction can occur with the TVT Abbrevo from scarification; correct? A. It could. Q. Obstruction resulting from scarification with regard to the TVT Abbrevo is not listed as an adverse reaction in the IFU which is marked as Exhibit 1657; correct? A. Correct. Q. And, Doctor, you would agree with me	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. Yes. Q. Doctor, chronic foreign body response is not listed in the TVT Abbrevo IFU as an adverse reaction; correct? A. Correct. Q. And I'm referring in that instance to the IFU marked as Exhibit 1659. A. Yes. Q. Do you understand that? A. Yes. Q. Doctor, foreign body response resulting in inflammation that is not transitory, it's not listed in the TVT Abbrevo IFU that is marked as Exhibit 1659, is it? A. No. Q. Foreign body response resulting in extrusion strike that. Chronic foreign body response resulting in extrusion is not listed in the Abbrevo IFU that has been marked as Exhibit 1659, does it? A. No.
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Q. And it doesn't appear in the IFU with 25 (Pause.)	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. That's correct. However, it doesn't say by the surgeon. It just says over-tensioning or overcorrection. MR. BARLOW: Move to strike as nonresponsive. THE WITNESS: Okay. BY MR. BARLOW: Q. Doctor, it says, too much tension applied to the mesh implant. Right? A. Yes. Q. That suggests surgeon error; correct? A. Or swelling. Q. Doctor, urinary obstruction can occur with the TVT Abbrevo from scarification; correct? A. It could. Q. Obstruction resulting from scarification with regard to the TVT Abbrevo is not listed as an adverse reaction in the IFU which is marked as Exhibit 1657; correct? A. Correct. Q. And, Doctor, you would agree with me that swelling does not appear anywhere in the TVT	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	A. Yes. Q. Doctor, chronic foreign body response is not listed in the TVT Abbrevo IFU as an adverse reaction; correct? A. Correct. Q. And I'm referring in that instance to the IFU marked as Exhibit 1659. A. Yes. Q. Do you understand that? A. Yes. Q. Doctor, foreign body response resulting in inflammation that is not transitory, it's not listed in the TVT Abbrevo IFU that is marked as Exhibit 1659, is it? A. No. Q. Foreign body response resulting in extrusion strike that. Chronic foreign body response resulting in extrusion is not listed in the Abbrevo IFU that has been marked as Exhibit 1659, does it? A. No. MR. GAGE: Let me ask you a question.

15 (Pages 346 to 349)

	Page 350		Page 352
1	MR. GAGE: All right. I'm sorry,	1	There are neuromuscular problems that
2	Alex. Go ahead.	2	can result from the Abbrevo other than leg pain;
3	BY MR. BARLOW:	3	correct?
4	Q. Doctor, chronic foreign body response	4	A. From the procedure in which the
5	that can result in erosion is not listed in the	5	Abbrevo is used?
6	adverse reactions in the IFU the Abbrevo IFU that	6	Q. There are neuromuscular problems from
7	has been marked as 1659; correct?	7	the use of the TVT Abbrevo that can result other
8	A. Correct.	8	than leg pain; correct?
9	Q. Chronic foreign body response that	9	A. Yes.
10	can result in fistula formation is not listed as a	10	Q. Okay.
11	possible adverse reaction in the IFU for the Abbrevo	11	Doctor, the leg pain that is
12	that has been marked as Exhibit 1659; correct?	12	discussed in the Abbrevo IFU is listed as transient
13	A. Correct.	13	leg pain lasting 24 to 48 hours; correct?
14	Q. The IFU for the Abbrevo that has been	14	A. That's correct.
15	marked as Exhibit 1659 does not list chronic foreign	15	Q. There is no warning regarding the
16	body response that can result in inflammation as a	16	possibility of leg pain lasting beyond 48 hours;
17	possible adverse reaction; correct?	17	correct?
18	A. That's correct.	18	A. Not in those words.
19	Q. And chronic inflammation is not	19	Q. So, Doctor, the TVT IFU strike
20	listed as a possible adverse reaction; correct?	20	that.
21	A. That's correct.	21	The TVT Abbrevo IFU that's marked as
22	Q. Doctor, the Abbrevo IFU that is	22	Exhibit 1659 does not list as an adverse reaction
23	marked as Exhibit 1659 does not list as an adverse	23	neuromuscular problems, including acute and/or
24	reaction or warn regarding mesh extrusion, exposure,	24	chronic pain in the groin, thigh, leg, pelvic and/or
25	or erosion into the vagina or other structures or	25	abdominal area, does it?
	Page 351		Page 353
1		1	
1 2	organs, does it?	1 2	A. No, it doesn't.
2	organs, does it? A. The vagina or other structures or	2	A. No, it doesn't.Q. And, Doctor, the TVT Abbrevo does not
2	organs, does it? A. The vagina or other structures or organs is not culled out.	2	 A. No, it doesn't. Q. And, Doctor, the TVT Abbrevo does not list as chronic thigh pain as an adverse
2 3 4	organs, does it? A. The vagina or other structures or organs is not culled out. Q. The IFU for the Abbrevo that is	2 3 4	A. No, it doesn't. Q. And, Doctor, the TVT Abbrevo does not list as chronic thigh pain as an adverse reaction, does it?
2 3 4 5	organs, does it? A. The vagina or other structures or organs is not culled out. Q. The IFU for the Abbrevo that is marked as Exhibit 1659 does not list as an adverse	2 3 4 5	 A. No, it doesn't. Q. And, Doctor, the TVT Abbrevo does not list as chronic thigh pain as an adverse reaction, does it? A. It does not.
2 3 4 5 6	organs, does it? A. The vagina or other structures or organs is not culled out. Q. The IFU for the Abbrevo that is marked as Exhibit 1659 does not list as an adverse reaction acute and/or chronic pain, does it?	2 3 4 5 6	 A. No, it doesn't. Q. And, Doctor, the TVT Abbrevo does not list as chronic thigh pain as an adverse reaction, does it? A. It does not. Q. It does not list chronic leg pain as
2 3 4 5	organs, does it? A. The vagina or other structures or organs is not culled out. Q. The IFU for the Abbrevo that is marked as Exhibit 1659 does not list as an adverse reaction acute and/or chronic pain, does it? A. No.	2 3 4 5 6 7	A. No, it doesn't. Q. And, Doctor, the TVT Abbrevo does not list as chronic thigh pain as an adverse reaction, does it? A. It does not. Q. It does not list chronic leg pain as a possible adverse reaction, does it?
2 3 4 5 6 7 8	organs, does it? A. The vagina or other structures or organs is not culled out. Q. The IFU for the Abbrevo that is marked as Exhibit 1659 does not list as an adverse reaction acute and/or chronic pain, does it? A. No. Q. The IFU for the Abbrevo that has been	2 3 4 5 6	A. No, it doesn't. Q. And, Doctor, the TVT Abbrevo does not list as chronic thigh pain as an adverse reaction, does it? A. It does not. Q. It does not list chronic leg pain as a possible adverse reaction, does it? A. No.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	organs, does it? A. The vagina or other structures or organs is not culled out. Q. The IFU for the Abbrevo that is marked as Exhibit 1659 does not list as an adverse reaction acute and/or chronic pain, does it? A. No. Q. The IFU for the Abbrevo that has been marked as Exhibit 1659 does not list as an adverse reaction pain with intercourse, which in some patients may not resolve, does it? A. No. Q. The IFU which for the strike that. The IFU for the TVT Abbrevo which has been marked as Exhibit 1659 does not list as a adverse reaction neuromuscular problems; correct? A. Only the leg pain noted in warnings and precautions. Q. Doctor, that the neuromuscular problems strike that.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	A. No, it doesn't. Q. And, Doctor, the TVT Abbrevo does not list as chronic thigh pain as an adverse reaction, does it? A. It does not. Q. It does not list chronic leg pain as a possible adverse reaction, does it? A. No. Q. Doctor, the TVT Abbrevo IFU that's marked as Exhibit 1659 does not state that the adverse reactions that may result from the Abbrevo may require surgical treatment, does it? A. It says some of them do. Q. Which ones does it say may result? A. The first adverse reaction, punctures or laceration of vessels, nerves, bladder, urethra, bowel may occur during needle passage and may require surgical repair. Q. Doctor, those are all adverse
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	organs, does it? A. The vagina or other structures or organs is not culled out. Q. The IFU for the Abbrevo that is marked as Exhibit 1659 does not list as an adverse reaction acute and/or chronic pain, does it? A. No. Q. The IFU for the Abbrevo that has been marked as Exhibit 1659 does not list as an adverse reaction pain with intercourse, which in some patients may not resolve, does it? A. No. Q. The IFU which for the strike that. The IFU for the TVT Abbrevo which has been marked as Exhibit 1659 does not list as a adverse reaction neuromuscular problems; correct? A. Only the leg pain noted in warnings and precautions. Q. Doctor, that the neuromuscular problems strike that. There are neuromuscular problems	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. No, it doesn't. Q. And, Doctor, the TVT Abbrevo does not list as chronic thigh pain as an adverse reaction, does it? A. It does not. Q. It does not list chronic leg pain as a possible adverse reaction, does it? A. No. Q. Doctor, the TVT Abbrevo IFU that's marked as Exhibit 1659 does not state that the adverse reactions that may result from the Abbrevo may require surgical treatment, does it? A. It says some of them do. Q. Which ones does it say may result? A. The first adverse reaction, punctures or laceration of vessels, nerves, bladder, urethra, bowel may occur during needle passage and may require surgical repair. Q. Doctor, those are all adverse reactions that may require surgical repair related to the procedure to implant it; correct? A. Correct.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	organs, does it? A. The vagina or other structures or organs is not culled out. Q. The IFU for the Abbrevo that is marked as Exhibit 1659 does not list as an adverse reaction acute and/or chronic pain, does it? A. No. Q. The IFU for the Abbrevo that has been marked as Exhibit 1659 does not list as an adverse reaction pain with intercourse, which in some patients may not resolve, does it? A. No. Q. The IFU which for the strike that. The IFU for the TVT Abbrevo which has been marked as Exhibit 1659 does not list as a adverse reaction neuromuscular problems; correct? A. Only the leg pain noted in warnings and precautions. Q. Doctor, that the neuromuscular problems strike that.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. No, it doesn't. Q. And, Doctor, the TVT Abbrevo does not list as chronic thigh pain as an adverse reaction, does it? A. It does not. Q. It does not list chronic leg pain as a possible adverse reaction, does it? A. No. Q. Doctor, the TVT Abbrevo IFU that's marked as Exhibit 1659 does not state that the adverse reactions that may result from the Abbrevo may require surgical treatment, does it? A. It says some of them do. Q. Which ones does it say may result? A. The first adverse reaction, punctures or laceration of vessels, nerves, bladder, urethra, bowel may occur during needle passage and may require surgical repair. Q. Doctor, those are all adverse reactions that may require surgical repair related to the procedure to implant it; correct? A. Correct. Q. With regard to adverse reactions that
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	organs, does it? A. The vagina or other structures or organs is not culled out. Q. The IFU for the Abbrevo that is marked as Exhibit 1659 does not list as an adverse reaction acute and/or chronic pain, does it? A. No. Q. The IFU for the Abbrevo that has been marked as Exhibit 1659 does not list as an adverse reaction pain with intercourse, which in some patients may not resolve, does it? A. No. Q. The IFU which for the strike that. The IFU for the TVT Abbrevo which has been marked as Exhibit 1659 does not list as a adverse reaction neuromuscular problems; correct? A. Only the leg pain noted in warnings and precautions. Q. Doctor, that the neuromuscular problems strike that. There are neuromuscular problems other than leg pain; correct?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. No, it doesn't. Q. And, Doctor, the TVT Abbrevo does not list as chronic thigh pain as an adverse reaction, does it? A. It does not. Q. It does not list chronic leg pain as a possible adverse reaction, does it? A. No. Q. Doctor, the TVT Abbrevo IFU that's marked as Exhibit 1659 does not state that the adverse reactions that may result from the Abbrevo may require surgical treatment, does it? A. It says some of them do. Q. Which ones does it say may result? A. The first adverse reaction, punctures or laceration of vessels, nerves, bladder, urethra, bowel may occur during needle passage and may require surgical repair. Q. Doctor, those are all adverse reactions that may require surgical repair related to the procedure to implant it; correct? A. Correct.

16 (Pages 350 to 353)

1	Page 354		Page 356
_	Exhibit 1659 does it state that there may there	1	
2	may be surgical treatment required, does it?	2	(Deposition Exhibit No. P-1660,
3	A. The device consists of the mesh and	3	9/18/15-Present TVT Exact IFU,
4	the needles to insert the mesh, so if you say due to	4	ETH.MESH.22129185 through
5	the device itself, I'd have to say that that's not	5	ETH.MESH.22129163 through ETH.MESH.22129191, was marked for
6	correct.	6	identification.)
7		7	idenuncation.)
8	Q. Doctor, the TVT Abbrevo IFU that's marked as Exhibit 1659 does not state that adverse	8	(Deposition Exhibit No. P-1661,
9		9	5/4/10-6/6/13 TVT Exact IFU,
10	reactions that may occur postoperatively may require	10	·
11	surgical treatment, does it? A. No.	11	ETH.MESH.05799233 through
12		12	ETH.MESH.05799239, was marked for
13	Q. And, Doctor, it does not the TVT	13	identification.)
	Abbrevo that's marked as Exhibit 1659 does not state		(Danastian Fability Na D 1662
14	that adverse reactions to the sling itself may	14	(Deposition Exhibit No. P-1662,
15	require surgical treatment, does it?	15	10/23/13-11/26/14 TVT Exact IFU,
16	A. No.	16	HMESH_ETH_03038566 through
17	Q. Doctor, the TVT Abbrevo IFU that's	17	HMESH_ETH_03038572, was marked for
18	marked as Exhibit 1659 does not state that one or	18	identification.)
19	more revision surgeries may be necessary to treat	19	
20	the adverse reactions that occur postoperatively,	20	(Deposition Exhibit No. P-1663,
21	does it?	21	8/12/14-9/9/15 TVT Exact IFU,
22	A. No.	22	ETH.MESH.02618012 through
23	Q. The TVT Abbrevo that's marked as	23	ETH.MESH.02618018, was marked for
24	Exhibit 1659 does not state that one or more	24	identification.)
25	revision surgeries may be necessary to treat adverse	25	
	Page 355		Page 357
1	reactions to the sling itself, does it?	1	(Deposition Exhibit No. P-1664,
2	A. No.	2	8/5/13-10/17/13 TVT Exact IFU,
3	Q. Doctor, the TVT Abbrevo IFU that's	3	ETH.MESH.10670138 through
4	marked as Exhibit 1659 does not state that in cases	4	ETH.MESH.10670144, was marked for
5	in which the Prolene mesh needs to be removed in	5	identification.)
6	part or whole, that significant dissection may be	6	'
7	required, does it?	7	THE VIDEO TECHNICIAN: The time is
	A. No.	8	11:12. We're back on the record.
8	Q. And, Doctor, nowhere in the TVT	١ ،	
8 9	Q. And, Doctor, nowhere in the 1 v i	9	BY MR. BARLOW:
	Abbrevo that's marked as Exhibit 1659 does it state	10	BY MR. BARLOW: Q. Okay, Doctor. We're going to turn
9			Q. Okay, Doctor. We're going to turn
9 10	Abbrevo that's marked as Exhibit 1659 does it state that the surgical repair for possible adverse	10	
9 10 11	Abbrevo that's marked as Exhibit 1659 does it state that the surgical repair for possible adverse reactions may not resolve the symptoms or the	10 11	Q. Okay, Doctor. We're going to turn now to the TVT Exact and we're going to try to shorten this process a little bit.
9 10 11 12	Abbrevo that's marked as Exhibit 1659 does it state that the surgical repair for possible adverse	10 11 12	Q. Okay, Doctor. We're going to turn now to the TVT Exact and we're going to try to shorten this process a little bit. I have handed you an exhibit that is
9 10 11 12 13	Abbrevo that's marked as Exhibit 1659 does it state that the surgical repair for possible adverse reactions may not resolve the symptoms or the adverse reactions, does it? A. No.	10 11 12 13	Q. Okay, Doctor. We're going to turn now to the TVT Exact and we're going to try to shorten this process a little bit. I have handed you an exhibit that is marked as P-1660; correct?
9 10 11 12 13 14	Abbrevo that's marked as Exhibit 1659 does it state that the surgical repair for possible adverse reactions may not resolve the symptoms or the adverse reactions, does it? A. No. MR. BARLOW: Okay, Doctor. I think	10 11 12 13 14	Q. Okay, Doctor. We're going to turn now to the TVT Exact and we're going to try to shorten this process a little bit. I have handed you an exhibit that is marked as P-1660; correct? A. Yes.
9 10 11 12 13 14 15	Abbrevo that's marked as Exhibit 1659 does it state that the surgical repair for possible adverse reactions may not resolve the symptoms or the adverse reactions, does it? A. No. MR. BARLOW: Okay, Doctor. I think we can set aside the Abbrevo stuff for now. We're	10 11 12 13 14 15	Q. Okay, Doctor. We're going to turn now to the TVT Exact and we're going to try to shorten this process a little bit. I have handed you an exhibit that is marked as P-1660; correct? A. Yes. Q. Okay.
9 10 11 12 13 14 15	Abbrevo that's marked as Exhibit 1659 does it state that the surgical repair for possible adverse reactions may not resolve the symptoms or the adverse reactions, does it? A. No. MR. BARLOW: Okay, Doctor. I think we can set aside the Abbrevo stuff for now. We're going to move on to the Exact.	10 11 12 13 14 15 16	Q. Okay, Doctor. We're going to turn now to the TVT Exact and we're going to try to shorten this process a little bit. I have handed you an exhibit that is marked as P-1660; correct? A. Yes. Q. Okay. And I believe that is the IFU that
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9 10 11 12 13 14 15 16 17 18 19 20 21	Abbrevo that's marked as Exhibit 1659 does it state that the surgical repair for possible adverse reactions may not resolve the symptoms or the adverse reactions, does it? A. No. MR. BARLOW: Okay, Doctor. I think we can set aside the Abbrevo stuff for now. We're going to move on to the Exact. MR. GAGE: Yeah, can we take a quick bathroom break? MR. BARLOW: Sure, sure. MR. GAGE: Let's just make it quick.	10 11 12 13 14 15 16 17 18 19 20 21	Q. Okay, Doctor. We're going to turn now to the TVT Exact and we're going to try to shorten this process a little bit. I have handed you an exhibit that is marked as P-1660; correct? A. Yes. Q. Okay. And I believe that is the IFU that has been in use from 9/18/2015 to the present day; correct? A. Yes. Q. And then I've handed you several
9 10 11 12 13 14 15 16 17 18 19 20 21 22	Abbrevo that's marked as Exhibit 1659 does it state that the surgical repair for possible adverse reactions may not resolve the symptoms or the adverse reactions, does it? A. No. MR. BARLOW: Okay, Doctor. I think we can set aside the Abbrevo stuff for now. We're going to move on to the Exact. MR. GAGE: Yeah, can we take a quick bathroom break? MR. BARLOW: Sure, sure. MR. GAGE: Let's just make it quick. THE VIDEO TECHNICIAN: The time is	10 11 12 13 14 15 16 17 18 19 20 21 22	Q. Okay, Doctor. We're going to turn now to the TVT Exact and we're going to try to shorten this process a little bit. I have handed you an exhibit that is marked as P-1660; correct? A. Yes. Q. Okay. And I believe that is the IFU that has been in use from 9/18/2015 to the present day; correct? A. Yes. Q. And then I've handed you several other IF well, strike that.
9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Abbrevo that's marked as Exhibit 1659 does it state that the surgical repair for possible adverse reactions may not resolve the symptoms or the adverse reactions, does it? A. No. MR. BARLOW: Okay, Doctor. I think we can set aside the Abbrevo stuff for now. We're going to move on to the Exact. MR. GAGE: Yeah, can we take a quick bathroom break? MR. BARLOW: Sure, sure. MR. GAGE: Let's just make it quick. THE VIDEO TECHNICIAN: The time is 10:50. We're going off the record.	10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q. Okay, Doctor. We're going to turn now to the TVT Exact and we're going to try to shorten this process a little bit. I have handed you an exhibit that is marked as P-1660; correct? A. Yes. Q. Okay. And I believe that is the IFU that has been in use from 9/18/2015 to the present day; correct? A. Yes. Q. And then I've handed you several other IF well, strike that. I've also handed you an Exhibit 1661
9 10 11 12 13 14 15 16 17 18 19 20 21 22	Abbrevo that's marked as Exhibit 1659 does it state that the surgical repair for possible adverse reactions may not resolve the symptoms or the adverse reactions, does it? A. No. MR. BARLOW: Okay, Doctor. I think we can set aside the Abbrevo stuff for now. We're going to move on to the Exact. MR. GAGE: Yeah, can we take a quick bathroom break? MR. BARLOW: Sure, sure. MR. GAGE: Let's just make it quick. THE VIDEO TECHNICIAN: The time is	10 11 12 13 14 15 16 17 18 19 20 21 22	Q. Okay, Doctor. We're going to turn now to the TVT Exact and we're going to try to shorten this process a little bit. I have handed you an exhibit that is marked as P-1660; correct? A. Yes. Q. Okay. And I believe that is the IFU that has been in use from 9/18/2015 to the present day; correct? A. Yes. Q. And then I've handed you several other IF well, strike that.

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1	Page 358		Page 360
1	use from May 4th, 2010 to June 6, 2013.	1	going to do is, I'm going to ask you questions
2	Do you have that?	2	regarding the adverse reactions that would be listed
3	A. Yes.	3	in the TVT Exact IFUs that are marked as Exhibits
4	Q. And is that correct?	4	1661 through 64.
5	A. Yes.	5	And I'm going to ask you that if your
6	Q. Okay.	6	answer needs to be different for any of the exhibits
7	Exhibit 1662 is the TVT Exact IFU	7	the IFUs that are Exhibits 1661 through 1664, you
8	that was in use from 10/23/13 until 11/26/14	8	tell me; otherwise, we're going to apply your answer
9	according to what has been produced to us; correct?	9	to each of those individually. Okay?
10	A. Yes.	10	THE WITNESS: I'm not sure I followed
11	Q. Exhibit 1663 is the TVT Exact IFU	11	that.
12	that has been represented to be in use from August	12	MR. BARLOW: Okay.
13	12, 2014 to September 9, 2015; is that correct?	13	THE WITNESS: I'm sorry.
14	A. Yes.	14	BY MR. BARLOW:
15	Q. 1664 is the TVT Exact IFU that has	15	Q. 1660's obviously different because
16	been represented to be in use from August 5th, 2013	16	that's the current IFU.
17	until October 17th, 2013; correct?	17	A. Right. Okay.
18	A. Yes.	18	Q. I'm going to be asking you questions
19	Q. Now, Doctor, on the break, I asked	19	about 1661 through 1664, which are the out-of-date
20	you to review Exhibit 1660 through 1664, and you had	20	IFUs and but I'm going to ask them collectively,
21	an opportunity to do that. Right?	21	with the consent of your counsel, and you're going
22	A. I did.	22	to point out to me, if you would, if there needs to
23	Q. Exhibit 1660 is the TVT Exact IFU	23	be a different answer for one of those. Otherwise,
24	that was put out as a result of the Health Canada	24	we're going to apply your answer individually to
25	inquiry; correct?	25	each one of those IFUs. Okay?
	Page 359		Page 361
1	A. Yes.	1	A. Okay. I
2	Q. With regard to Exhibit 1661 through	2	Q. Is that agreeable?
3	1664, you understand I'm going to be questioning you	3	A. Yes.
4	regarding warnings and adverse reactions, just as we	4	MR. BARLOW: Counsel, is that
1			
5	had been discussing earlier; correct?	5	agreeable?
6	A. Correct.	5 6	agreeable? MR. GAGE: Yeah, that's fine.
6 7	A. Correct.Q. With regard to the adverse reactions	5 6 7	agreeable? MR. GAGE: Yeah, that's fine. MR. BARLOW: Okay.
6 7 8	A. Correct.Q. With regard to the adverse reactionslisted on Exhibit 1640 and Exhibit 1641, have you	5 6 7 8	agreeable? MR. GAGE: Yeah, that's fine. MR. BARLOW: Okay. BY MR. BARLOW:
6 7 8 9	A. Correct. Q. With regard to the adverse reactions listed on Exhibit 1640 and Exhibit 1641, have you had an opportunity to review Exhibits 1661 through	5 6 7 8 9	agreeable? MR. GAGE: Yeah, that's fine. MR. BARLOW: Okay. BY MR. BARLOW: Q. Doctor, at the time of the launch of
6 7 8 9 10	A. Correct. Q. With regard to the adverse reactions listed on Exhibit 1640 and Exhibit 1641, have you had an opportunity to review Exhibits 1661 through 1664 and determine that your answers would be the	5 6 7 8 9	agreeable? MR. GAGE: Yeah, that's fine. MR. BARLOW: Okay. BY MR. BARLOW: Q. Doctor, at the time of the launch of the TVT Exact, it was known to Ethicon that there
6 7 8 9 10 11	A. Correct. Q. With regard to the adverse reactions listed on Exhibit 1640 and Exhibit 1641, have you had an opportunity to review Exhibits 1661 through 1664 and determine that your answers would be the same with regard to all of those IFUs regarding the	5 6 7 8 9 10 11	agreeable? MR. GAGE: Yeah, that's fine. MR. BARLOW: Okay. BY MR. BARLOW: Q. Doctor, at the time of the launch of the TVT Exact, it was known to Ethicon that there could be foreign body response to the Exact that
6 7 8 9 10 11 12	A. Correct. Q. With regard to the adverse reactions listed on Exhibit 1640 and Exhibit 1641, have you had an opportunity to review Exhibits 1661 through 1664 and determine that your answers would be the same with regard to all of those IFUs regarding the adverse reactions listed in 1640 and 1641?	5 6 7 8 9 10 11	agreeable? MR. GAGE: Yeah, that's fine. MR. BARLOW: Okay. BY MR. BARLOW: Q. Doctor, at the time of the launch of the TVT Exact, it was known to Ethicon that there could be foreign body response to the Exact that would result in inflammation, extrusion, erosion,
6 7 8 9 10 11 12 13	A. Correct. Q. With regard to the adverse reactions listed on Exhibit 1640 and Exhibit 1641, have you had an opportunity to review Exhibits 1661 through 1664 and determine that your answers would be the same with regard to all of those IFUs regarding the adverse reactions listed in 1640 and 1641? A. Let me just understand. My answers	5 6 7 8 9 10 11 12	agreeable? MR. GAGE: Yeah, that's fine. MR. BARLOW: Okay. BY MR. BARLOW: Q. Doctor, at the time of the launch of the TVT Exact, it was known to Ethicon that there could be foreign body response to the Exact that would result in inflammation, extrusion, erosion, exposure, and fistula formation; correct?
6 7 8 9 10 11 12 13	A. Correct. Q. With regard to the adverse reactions listed on Exhibit 1640 and Exhibit 1641, have you had an opportunity to review Exhibits 1661 through 1664 and determine that your answers would be the same with regard to all of those IFUs regarding the adverse reactions listed in 1640 and 1641? A. Let me just understand. My answers will be the same for all of these?	5 6 7 8 9 10 11 12 13	agreeable? MR. GAGE: Yeah, that's fine. MR. BARLOW: Okay. BY MR. BARLOW: Q. Doctor, at the time of the launch of the TVT Exact, it was known to Ethicon that there could be foreign body response to the Exact that would result in inflammation, extrusion, erosion, exposure, and fistula formation; correct? A. Yes.
6 7 8 9 10 11 12 13 14 15	A. Correct. Q. With regard to the adverse reactions listed on Exhibit 1640 and Exhibit 1641, have you had an opportunity to review Exhibits 1661 through 1664 and determine that your answers would be the same with regard to all of those IFUs regarding the adverse reactions listed in 1640 and 1641? A. Let me just understand. My answers will be the same for all of these? Q. Yes.	5 6 7 8 9 10 11 12 13 14 15	agreeable? MR. GAGE: Yeah, that's fine. MR. BARLOW: Okay. BY MR. BARLOW: Q. Doctor, at the time of the launch of the TVT Exact, it was known to Ethicon that there could be foreign body response to the Exact that would result in inflammation, extrusion, erosion, exposure, and fistula formation; correct? A. Yes. Q. At the time of the launch of the TVT
6 7 8 9 10 11 12 13 14 15	A. Correct. Q. With regard to the adverse reactions listed on Exhibit 1640 and Exhibit 1641, have you had an opportunity to review Exhibits 1661 through 1664 and determine that your answers would be the same with regard to all of those IFUs regarding the adverse reactions listed in 1640 and 1641? A. Let me just understand. My answers will be the same for all of these? Q. Yes. A. Yes.	5 6 7 8 9 10 11 12 13 14 15 16	agreeable? MR. GAGE: Yeah, that's fine. MR. BARLOW: Okay. BY MR. BARLOW: Q. Doctor, at the time of the launch of the TVT Exact, it was known to Ethicon that there could be foreign body response to the Exact that would result in inflammation, extrusion, erosion, exposure, and fistula formation; correct? A. Yes. Q. At the time of the launch of the TVT Exact, it was known to Ethicon that mesh extrusion,
6 7 8 9 10 11 12 13 14 15 16 17	A. Correct. Q. With regard to the adverse reactions listed on Exhibit 1640 and Exhibit 1641, have you had an opportunity to review Exhibits 1661 through 1664 and determine that your answers would be the same with regard to all of those IFUs regarding the adverse reactions listed in 1640 and 1641? A. Let me just understand. My answers will be the same for all of these? Q. Yes. A. Yes. Q. Okay.	5 6 7 8 9 10 11 12 13 14 15 16 17	agreeable? MR. GAGE: Yeah, that's fine. MR. BARLOW: Okay. BY MR. BARLOW: Q. Doctor, at the time of the launch of the TVT Exact, it was known to Ethicon that there could be foreign body response to the Exact that would result in inflammation, extrusion, erosion, exposure, and fistula formation; correct? A. Yes. Q. At the time of the launch of the TVT Exact, it was known to Ethicon that mesh extrusion, exposure, or erosion into the vagina or other
6 7 8 9 10 11 12 13 14 15 16 17	A. Correct. Q. With regard to the adverse reactions listed on Exhibit 1640 and Exhibit 1641, have you had an opportunity to review Exhibits 1661 through 1664 and determine that your answers would be the same with regard to all of those IFUs regarding the adverse reactions listed in 1640 and 1641? A. Let me just understand. My answers will be the same for all of these? Q. Yes. A. Yes. Q. Okay. MR. GAGE: And to clarify, "these"	5 6 7 8 9 10 11 12 13 14 15 16 17	agreeable? MR. GAGE: Yeah, that's fine. MR. BARLOW: Okay. BY MR. BARLOW: Q. Doctor, at the time of the launch of the TVT Exact, it was known to Ethicon that there could be foreign body response to the Exact that would result in inflammation, extrusion, erosion, exposure, and fistula formation; correct? A. Yes. Q. At the time of the launch of the TVT Exact, it was known to Ethicon that mesh extrusion, exposure, or erosion into the vagina or other structures or organs could result from the use of
6 7 8 9 10 11 12 13 14 15 16 17 18	A. Correct. Q. With regard to the adverse reactions listed on Exhibit 1640 and Exhibit 1641, have you had an opportunity to review Exhibits 1661 through 1664 and determine that your answers would be the same with regard to all of those IFUs regarding the adverse reactions listed in 1640 and 1641? A. Let me just understand. My answers will be the same for all of these? Q. Yes. A. Yes. Q. Okay. MR. GAGE: And to clarify, "these" the word "these" does not include P-1660, which is	5 6 7 8 9 10 11 12 13 14 15 16 17 18	agreeable? MR. GAGE: Yeah, that's fine. MR. BARLOW: Okay. BY MR. BARLOW: Q. Doctor, at the time of the launch of the TVT Exact, it was known to Ethicon that there could be foreign body response to the Exact that would result in inflammation, extrusion, erosion, exposure, and fistula formation; correct? A. Yes. Q. At the time of the launch of the TVT Exact, it was known to Ethicon that mesh extrusion, exposure, or erosion into the vagina or other structures or organs could result from the use of the TVT Exact.
6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	A. Correct. Q. With regard to the adverse reactions listed on Exhibit 1640 and Exhibit 1641, have you had an opportunity to review Exhibits 1661 through 1664 and determine that your answers would be the same with regard to all of those IFUs regarding the adverse reactions listed in 1640 and 1641? A. Let me just understand. My answers will be the same for all of these? Q. Yes. A. Yes. Q. Okay. MR. GAGE: And to clarify, "these" the word "these" does not include P-1660, which is the current	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	agreeable? MR. GAGE: Yeah, that's fine. MR. BARLOW: Okay. BY MR. BARLOW: Q. Doctor, at the time of the launch of the TVT Exact, it was known to Ethicon that there could be foreign body response to the Exact that would result in inflammation, extrusion, erosion, exposure, and fistula formation; correct? A. Yes. Q. At the time of the launch of the TVT Exact, it was known to Ethicon that mesh extrusion, exposure, or erosion into the vagina or other structures or organs could result from the use of the TVT Exact. A. Yes.
6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. Correct. Q. With regard to the adverse reactions listed on Exhibit 1640 and Exhibit 1641, have you had an opportunity to review Exhibits 1661 through 1664 and determine that your answers would be the same with regard to all of those IFUs regarding the adverse reactions listed in 1640 and 1641? A. Let me just understand. My answers will be the same for all of these? Q. Yes. A. Yes. Q. Okay. MR. GAGE: And to clarify, "these" the word "these" does not include P-1660, which is the current	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	agreeable? MR. GAGE: Yeah, that's fine. MR. BARLOW: Okay. BY MR. BARLOW: Q. Doctor, at the time of the launch of the TVT Exact, it was known to Ethicon that there could be foreign body response to the Exact that would result in inflammation, extrusion, erosion, exposure, and fistula formation; correct? A. Yes. Q. At the time of the launch of the TVT Exact, it was known to Ethicon that mesh extrusion, exposure, or erosion into the vagina or other structures or organs could result from the use of the TVT Exact. A. Yes. Q. It was known at the time of the
6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. Correct. Q. With regard to the adverse reactions listed on Exhibit 1640 and Exhibit 1641, have you had an opportunity to review Exhibits 1661 through 1664 and determine that your answers would be the same with regard to all of those IFUs regarding the adverse reactions listed in 1640 and 1641? A. Let me just understand. My answers will be the same for all of these? Q. Yes. A. Yes. Q. Okay. MR. GAGE: And to clarify, "these" the word "these" does not include P-1660, which is the current MR. BARLOW: Current. THE WITNESS: Correct.	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	agreeable? MR. GAGE: Yeah, that's fine. MR. BARLOW: Okay. BY MR. BARLOW: Q. Doctor, at the time of the launch of the TVT Exact, it was known to Ethicon that there could be foreign body response to the Exact that would result in inflammation, extrusion, erosion, exposure, and fistula formation; correct? A. Yes. Q. At the time of the launch of the TVT Exact, it was known to Ethicon that mesh extrusion, exposure, or erosion into the vagina or other structures or organs could result from the use of the TVT Exact. A. Yes. Q. It was known at the time of the launch of the TVT Exact that mesh extrusion,
6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. Correct. Q. With regard to the adverse reactions listed on Exhibit 1640 and Exhibit 1641, have you had an opportunity to review Exhibits 1661 through 1664 and determine that your answers would be the same with regard to all of those IFUs regarding the adverse reactions listed in 1640 and 1641? A. Let me just understand. My answers will be the same for all of these? Q. Yes. A. Yes. Q. Okay. MR. GAGE: And to clarify, "these" the word "these" does not include P-1660, which is the current MR. BARLOW: Current. THE WITNESS: Correct. MR. GAGE: Abbrevo IFU.	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	agreeable? MR. GAGE: Yeah, that's fine. MR. BARLOW: Okay. BY MR. BARLOW: Q. Doctor, at the time of the launch of the TVT Exact, it was known to Ethicon that there could be foreign body response to the Exact that would result in inflammation, extrusion, erosion, exposure, and fistula formation; correct? A. Yes. Q. At the time of the launch of the TVT Exact, it was known to Ethicon that mesh extrusion, exposure, or erosion into the vagina or other structures or organs could result from the use of the TVT Exact. A. Yes. Q. It was known at the time of the launch of the TVT Exact that mesh extrusion, exposure, or erosion into the vagina or other
6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. Correct. Q. With regard to the adverse reactions listed on Exhibit 1640 and Exhibit 1641, have you had an opportunity to review Exhibits 1661 through 1664 and determine that your answers would be the same with regard to all of those IFUs regarding the adverse reactions listed in 1640 and 1641? A. Let me just understand. My answers will be the same for all of these? Q. Yes. A. Yes. Q. Okay. MR. GAGE: And to clarify, "these" the word "these" does not include P-1660, which is the current MR. BARLOW: Current. THE WITNESS: Correct.	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	agreeable? MR. GAGE: Yeah, that's fine. MR. BARLOW: Okay. BY MR. BARLOW: Q. Doctor, at the time of the launch of the TVT Exact, it was known to Ethicon that there could be foreign body response to the Exact that would result in inflammation, extrusion, erosion, exposure, and fistula formation; correct? A. Yes. Q. At the time of the launch of the TVT Exact, it was known to Ethicon that mesh extrusion, exposure, or erosion into the vagina or other structures or organs could result from the use of the TVT Exact. A. Yes. Q. It was known at the time of the launch of the TVT Exact that mesh extrusion,

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Page 362 Page 364 1 A. Yes. 1 treatment; correct? 2 2 O. It was known to Ethicon at the time A. Correct. 3 3 of the launch of the TVT Exact that acute and/or O. It was known at the time of the 4 4 chronic pain could result from the TVT Exact; launch of the TVT Exact that one or more revision 5 correct? 5 surgeries may be necessary to treat adverse 6 6 reactions from the TVT Exact; correct? A. Yes. 7 7 Q. It was known at the time of the A. From the use of the TVT Exact, yes. 8 8 launch of the TVT Exact that pain with intercourse, O. Well, one or more revision surgeries 9 which in some patients may not resolve, could result 9 may be necessary to treat adverse reactions that 10 from the use of the TVT Exact; correct? 10 result from the Exact sling itself; correct? 11 11 A. Yes. A. Yes. 12 12 Q. It was also known by Ethicon that Q. And that was known at the time of its launch. Right? 13 pain with intercourse, which in some patients may 13 14 not resolve, could result from the TVT Exact sling 14 Yes. A. 15 itself: correct? 15 O. Doctor, it was known by Ethicon at the time of the launch of the TVT Exact that in 16 Can you ask that again, please? 16 A. 17 It was known at the time of the 17 cases where the Prolene mesh needed to be removed in Q. 18 launch of the TVT Exact that pain with intercourse, 18 whole or in part, significant dissection may be 19 which in some patients may not resolve, could result 19 required; correct? 20 20 from the TVT Exact. A. The whole part, yes. The part part, 21 From the use of TVT Exact in that 21 removed in part, may not require --A. 22 procedure. 22 Q. It depends on how big a part. Right? 23 Well, that and where it -- from where 23 Q. A. 24 Doctor, with regard to the -- strike 24 it needs to be removed. If you'd like further 25 explanation, I'd be happy to give it to you. 25 that. Page 365 Page 363 Okay. What would be the distinction? 1 It was known at the time of the 1 Q. 2 launch of the TVT Exact that neuromuscular problems, 2 Well, one of the times where part of A. 3 including acute and/or chronic pain in the groin, 3 the TVT Exact, or really any of the other TVTs, 4 thigh, leg, pelvic and abdominal area could occur 4 might need to be removed is if it is exposed in the 5 with the TVT Exact; correct? 5 vagina; and in that case, it doesn't require a 6 No, there was no -- there was no 6 dissection of any significance. It's something that 7 7 can be done in the office with a scissors, where a thought that pain in the thigh or leg --8 8 Is that because the TVT Exact is a small piece that's exposed is just removed. O. 9 9 retropubic approach? And, Doctor, there are other -- and I 10 A. That's correct. 10 need to object as nonresponsive except to the extent 11 Okay. 11 he was answering with regard to the Exact, because Q. 12 So let me ask it a different way: 12 that's where our questions are -- that's what my Doctor, with regard to -- strike that. 13 questions are directed to. 13 14 It was known at the time of the 14 With regard to the TVT Exact, there 15 launch of the TVT Exact that neuromuscular problems, 15 may be repairs that need to -- removals that need to 16 including acute and/or chronic pain in the groin, 16 occur that go beyond just the -- a small exposure 17 pelvic and abdominal area could result from the TVT 17 that can be done in office; correct? Exact; correct? 18 18 A. Correct. 19 19 A. From the use of the TVT Exact in that And when those surgeries to remove 20 20 portions of the TVT Exact go beyond just the portion procedure, yes. 21 Okay. 21 that would be exposed -- small portion under the Q. 22 22 urethra, if it requires greater -- strike that. Doctor, it was known at the time of 23 the launch of the TVT Exact that the adverse There are removals of TVT Exact mesh 23 24 reactions that we've been discussing could -- that 24 that require greater dissection when you don't could result from the TVT Exact may require surgical 25 remove the whole device; correct? 25

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Page 366 Page 368 1 A. That's correct. 1 At the time of the launch of the TVT 2 2 Q. In fact, it's very difficult to ever Exact, it would have been reasonable to include in 3 3 remove the entire device; correct? the adverse reactions that mesh exposure, extrusion, 4 It's a difficult surgery, yes. 4 or erosion into the vagina or other structures or 5 And so it would be true that when the 5 organs could occur; correct? Q. 6 6 Prolene mesh needs to be removed in part, if it's a A. Yes. 7 significant part, significant dissection may be 7 Q. At the time of the launch of the TVT 8 8 required; correct? Exact, it would have been reasonable to list as a That's correct. 9 A. 9 possible adverse reaction that acute and/or chronic 10 Q. And that was something that was known 10 pain could result; correct? 11 11 to Ethicon at the time of the launch of the TVT A. Yes. 12 At the time of the launch of the TVT 12 Exact: correct? Q. Exact, it would have been reasonable to list as an 13 A. Yes. 13 14 14 adverse reaction that pain with intercourse, which O. And that's why you used the language 15 may be required as opposed to will be required. 15 in some patients may not resolve, could result; 16 Right? 16 correct? 17 17 Yes. A. That's correct. A. 18 Q. Doctor, with regard to -- strike 18 Q. At the time of the launch of the TVT 19 19 that. Exact, it would have been reasonable to list as an 20 20 At the time of the launch of the TVT adverse reaction that neuromuscular problems, 21 Exact, it was known that use of the Exact could 21 including acute and/or chronic pain in the groin, 22 result in de novo urge incontinence; correct? 22 pelvic and/or abdominal area could result; correct? 23 23 Yes. A. Yes. A. 24 24 Q. At the time of the launch of the TVT Q. At the time of the launch of the TVT Exact, it was known to Ethicon that implantation --25 Exact, it would have been reasonable to list as a Page 367 Page 369 1 strike that. 1 possible adverse reaction -- strike that. 2 2 At the time of the launch of the TVT Doctor, at the time of the launch of 3 the TVT Exact, it was known that a potential adverse 3 Exact, it would have been reasonable to include that 4 4 reaction was de novo urinary frequency; correct? the adverse reactions of the Exact may require 5 Yes. 5 A. surgical treatment; correct? 6 6 Q. At the time of the launch of the TVT A. Yes. 7 Exact, it was known that a possible adverse reaction 7 At the time of the launch of the TVT 8 8 was de novo urinary retention; correct? Exact, it would have been reasonable to include in 9 9 the IFU that one or more revision surgeries may be A. Yes. 10 Q. At the time of the launch of the TVT 10 necessary to treat adverse reactions to the TVT Exact, it was known by Ethicon that a possible 11 Exact; correct? 11 adverse reaction was de novo urinary obstruction; 12 12 A. Yes. 13 correct? 13 At the time of the launch of the TVT 14 14 Exact, it would have been reasonable to include in A. Yes. At the time of the launch of the TVT 15 O. 15 the adverse reactions in the IFU that in cases in 16 Exact, it was known by Ethicon that a possible 16 which the Prolene mesh needs to be removed in part adverse reaction was de novo voiding dysfunction; 17 or whole, significant dissection may be required; 17 correct? 18 correct? 18 19 19 A. Yes. A. Yes. 20 20 O. Doctor, at the time of the launch of At the time of the launch of the TVT 21 the TVT Exact, it would have been reasonable to warn 21 Exact, it would have been reasonable to include in 22 22 that there could be foreign body response resulting the adverse reactions section that de novo urge in inflammation, extrusion, erosion, exposure, and 23 incontinence could occur; correct? 23 24 fistula formation as an adverse reaction; correct? 24 A. Yes. 25 25 A. Yes. At the time of the launch of the TVT Q.

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Page 370 Page 372 Exact, it would have been reasonable to include as a 1 vagina or other organs. 2 2 possible adverse reaction that de novo urinary Okay. Q. 3 3 frequency could occur; correct? Doctor -- I'm going to object as 4 4 nonresponsive. A. Yes. 5 Q. At the time of the launch of the TVT 5 Doctor, the words mesh extrusion, 6 Exact, it would have been reasonable to include in 6 exposure, or erosion into the vagina or other 7 7 the adverse reactions section that urinary retention structures or organs does not appear in the adverse 8 8 reactions section of the TVT Exact IFU, does it? could occur; correct? 9 9 A. Yes. Right. 10 10 Q. At the time of the launch of the TVT MR. GAGE: Object to form. 11 11 Exact, it would have been reasonable to include in THE WITNESS: The vagina and other organs aren't spelled out, but the other words are 12 the adverse reactions that urinary obstruction could 12 13 occur; correct? 13 there. 14 14 MR. BARLOW: Object as nonresponsive. A. Yes. 15 15 O. And at the time of the launch of the What did I mess up, Bill? MR. GAGE: You said -- when you said 16 TVT Exact, it would have been reasonable to include 16 17 that de novo voiding dysfunction could occur; 17 "the words" and then you listed, if you said "the 18 correct? 18 phrase," it would not be objectionable, but because 19 A. 19 some of the words appear and some don't, that's why Yes. 20 20 O. Okay, Doctor. Turning to Exhibits I objected. 21 1661 and -- through 1664, Doctor, the TVT IFU for 21 MR. BARLOW: I understand. 22 Exact -- strike that. 22 BY MR. BARLOW: MS. KABBASH: I think this is harder 23 23 Q. Doctor, the phrase mesh extrusion, 24 exposure, or erosion into the vagina or other 24 than a normal deposition. 25 MR. BARLOW: It is. Yes, I can 25 structures or organs does not appear in the TVT Page 371 Page 373 1 babble more fluently when I'm just asking regular 1 Exact IFU, does it? 2 2 questions than kind of these formal questions, A. That's correct. 3 3 but... It's not noted that the extrusion, 4 BY MR. BARLOW: 4 exposure, or erosion can be into the vagina or other 5 5 Doctor, in the TVT Exact IFU, chronic structures or organs; correct? 6 foreign body response resulting in inflammation, 6 A. Correct. 7 extrusion, erosion, exposure, or fistula formation 7 The TVT Exact IFU does not include a 8 8 is not listed: correct? warning regarding acute and/or chronic pain, does 9 9 it? A. The word chronic is not mentioned. 10 Q. And to the extent foreign body 10 A. That's correct. response is discussed at all, it is characterized as 11 Doctor, the TVT IFU -- Exact IFU does 11 0. 12 being transitory; correct? 12 not include a warning regarding pain with 13 That's correct. 13 A. intercourse, which in some patients may not resolve; 14 14 O. And there is -- we know that there correct? 15 can be a chronic foreign body response with the TVT 15 Α. Correct. 16 Q. That's not listed in the adverse 16 Exact; correct? Histologically chronic. 17 17 A. reactions: correct? That's correct? 18 18 That's correct. Q. A. 19 19 A. Yes. The TVT Exact IFU does not list 20 20 neuromuscular problems, including acute and/or O. Doctor, the adverse reactions listed 21 in the TVT Exact IFU do not include mesh extrusion, 21 chronic pain in the groin, pelvis and/or abdominal 22 area, does it? 22 exposure, or erosion into the vagina or other structures or organs, do they? 23 23 That's correct. A. 24 Well, it includes extrusion, erosion, 24 O. The TVT Exact IFU does not include a and fistula formation, but it doesn't specify the 25 warning or information that adverse reactions to the 25

21 (Pages 370 to 373)

Page 374 Page 376 1 Exact may require surgical treatment, does it? 1 that it extended past the TVT Exact, which was the 2 2 A. It does not. subject of the question, but let me ask it this way. 3 3 Q. The TVT Exact IFU does not include a Doctor, urge incontinence is not 4 4 included in the adverse reactions section of the TVT statement or information that one or more revision surgeries may be necessary to treat the adverse 5 Exact IFU, does it? 6 6 reactions to the Exact, does it? A. No. 7 7 A. It does not. Q. Or is it. Yeah. 8 8 O. With regard to the mention of The TVT Exact IFU does not state that 9 in cases in which the Prolene mesh needs to be 9 detrusor instability in the warnings and precautions 10 removed in part or whole, that significant 10 section, that is -- that warning is intended to make 11 dissection may be required, does it? 11 the surgeon aware of the possibility of de novo 12 It does not. detrusor instability as a result of surgical A. 12 13 O. And the TVT Exact IFU does not state 13 technique; correct? 14 that even when multiple surgery -- strike that. 14 There's a specific warning about A. The TVT Exact IFU does not state that 15 15 implanting the Gynecare TVT Exact, but the sentence 16 when one or more revision surgeries are performed, 16 begins: As with other incontinence procedures, de 17 they may not resolve or cure the adverse reactions 17 novo detrusor instability may occur. 18 to the Exact; correct? 18 And that would -- and read as a 19 A. Correct. 19 whole, that's directed toward warning surgeons not 20 20 O. Doctor, the TVT Exact IFU does not to put the Exact in too tightly; correct? 21 state that de novo urge incontinence can result from 21 Well, but it also qualifies that this 22 the Exact, does it? 22 is a part of any incontinence surgery, whether or 23 23 MR. GAGE: Objection to the form. not the Exact is used or any other -- it's a general THE WITNESS: Actually, it does. 24 24 warning for incontinence procedures with some --25 25 MR. BARLOW: Okay. with a specific warning of one thing they can do to Page 375 Page 377 1 THE WITNESS: And I really just 1 try to avoid it with this procedure. 2 discovered this looking at all these IFUs side by 2 Q. Okay. 3 side, as you asked me to do; and I noticed that in 3 Doctor, with regard to urinary 4 warnings and precautions, there's a statement that 4 frequency, urinary frequency is not included in the 5 says: As with other incontinence procedures, de 5 adverse reactions section of the TVT Exact IFU, does 6 novo detrusor instability, which is the medical term 6 it? 7 for urge incontinence, may occur following the 7 A. No. 8 8 Gynecare TVT Exact continence system procedure. To O. The TVT Exact IFU adverse reactions 9 minimize this risk, make sure -- I can go on, but --9 section does not include urinary retention, does it? 10 MR. BARLOW: Make sure that -- go 10 A. Only in -- with reference to urinary 11 ahead. Finish the --11 tract obstruction. 12 THE WITNESS: Make sure to place the 12 The specific issue of urinary 13 implant tension free in the mid-urethral position. 13 retention does not appear in the TVT Exact IFU 14 MR. BARLOW: Okay. 14 adverse reactions section, does it? 15 THE WITNESS: And, unfortunately, 15 The words don't appear. A. 16 that's going to modify or amend many of the answers 16 Q. Okay. 17 that I gave today and yesterday, because I just 17 Urinary obstruction -- strike that. really found this. I was looking for the words urge 18 18 Doctor, the TVT Exact adverse 19 incontinence, and detrusor instability just kind of 19 reactions does not include urinary obstruction 20 went by and I just discovered it in reviewing these 20 resulting from scarification of the TVT Exact, does 21 documents. 21 it? 22 22 MR. BARLOW: All right. A. Just check -- no. 23 Doctor, the TVT Exact IFU does not BY MR. BARLOW: 23 Q. 24 Doctor, the -- let's do it this way 24 include voiding dysfunction as a result of the TVT 25 -- I need to object as nonresponsive to the extent 25 Exact sling itself, does it?

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A. Those words are not included, but voiding dysfunctions are discussed. Q. There are other voiding dysfunctions other than obstruction; correct? A. Right. Detrusor instability is another one and that's in the warnings. Q. Doctor, of the adverse reactions which of those? In the Helf in the warnings and precautions section, not to the Helf in the warnings and precautions section, not to the Helf in the warnings and precautions section, not to the Helf in the warnings and precautions section, not to the Helf in the warnings and precautions section, not to the Helf in the warnings and precautions section, not to the Helf in the warnings and precautions section, not to the Helf in the warnings and precautions section, not to the Helf in the warnings and precautions section, not to the Helf in the warnings and precautions section, not to the Helf in the warnings and precautions section, not to the Helf in the warnings and precautions section, not to the Helf in the warnings and precautions discovery was produced, the document of discovery was produced, the document dis		Page 378		Page 380
voiding dysfunctions are discussed. Q. There are other woiding - there are dother woiding dysfunctions other than obstruction; correct? A. Right. Detrusor instability is another one and that's in the warnings. Q. Doctor, of the adverse reactions yellow the following of the discovery of the discovery of the discovery was produced, in advance of this discovery was pr	1	A Those words are not included but	1	MR_FREESE: I mean I'm going to go
3 MR. GAGE: I mean, you know what I'm a talking about. 5 correct? 6 A. Right. Detrusor instability is another one and that's in the warnings. 8 Q. Doctor, of the adverse reactions listed on 1641, detrusor instability implicates which of those? 10 which of those? 11 A. Detrusor instability is included in the IPU in the warnings and precautions section, not in the adverse reactions section. 12 the IPU in the warnings and precautions section, not in the adverse reactions section. 13 in the adverse reactions section, not in the adverse reactions section. 14 MR. BARLOW: At this time, I'm going to urm the question. 15 as nonresponsive. 16 BY MR. BARLOW: Okay. I need to object in the adverse reactions is section in the adverse reactions listed on 1641.—Exhibit 1641? 16 BY MR. BARLOW: 17 MR. GAGE: He's asking about—he's which, if any, of the urinary adverse reactions listed on 1641.—Exhibit 1641? 18 miplicates which, if any, of the urinary adverse question. 19 THE WITNESS: Oh, I'm sorry. 20 MR. GAGE: So would you now— 21 THE WITNESS: I misunderstood. 21 MR. GAGE: So would you now— 22 THE WITNESS: Yeah. 23 THE WITNESS: Yeah. 24 THE WITNESS: Yeah. 25 BY MR. BARLOW: 26 Q. Doctor, detrusor instability implicates which, if one you the whole thing again, what we talked about on the record yesterday: The MDL's position is, is that due to the volume and manner in the point of the univary adverse reactions listed on 1641.—Exhibit 1641? 26 MR. GAGE: So would you now— 27 THE WITNESS: Oh, I'm sorry. 28 THE WITNESS: I misunderstood. 29 MR. GAGE: Alex, reask the question. 29 Code of the detrusor instability implicates which, if any of the urinary adverse reactions is, that due to the volume and manner in the point of the tree of the detrusor instability implicates which, if any of the urinary adverse reactions is, that due to the volume and manner in the adverse reactions is, that due to the volume and manner in the adverse reactions is, that due to the volume and manner in the adverse reactions is, that due to the volume and manner		·		
4 other voiding dysfunctions other than obstruction; correct? 5 A. Right. Detrusor instability is another one and that's in the warnings. 9 Doctor, of the adverse reactions which of those? 11 A. Detrusor instability is included in the adverse reactions section, or in the adverse reactions section. 12 If in the warnings and precautions section, and the adverse reactions section. 13 If the William of the adverse reactions section which of the service of the adverse reaction section. 14 If william of the service of the adverse reaction section which are the If the service of the adverse reaction section. 15 BY MR. BARLOW: Okay. I need to object as an onresponsive. 16 BY MR. BARLOW: Okay. I need to object as an onresponsive. 17 Q. De novo detrusor instability implicates which, if any, of the urinary adverse reaction slited on lof4. Exhibit 1641? 18 Implicates which, if any, of the urinary adverse reaction slited on lof4. Exhibit 1641? 19 MR. GAGE: He's asking about - he's wanting you to look at this list when you answer the question. 20 Q. MR. GAGE: He's asking about - he's wanting you to look at this list when you answer the question? 11 THE WITNESS: Oh, I'm sorry. 22 A THE WITNESS: I misunderstood. 23 MR. GAGE: He's asking about - he's wanting you to look at this list when you answer the question? 24 THE WITNESS: Yeah. 25 PAGE 3 A Ves. 26 Q. Doctor, detrusor instability implicates which of the urinary conditions on Exhibit 1641? 27 A Urge incontinence. 28 Q. Okay. 29 A. Although some patients with detrusor implicates which of the urinary sold the ferror instability have urinary frequency, also. 29 Q. Because of the detrusor instability in time is 11:41. We're going off the record. 29 A. Ves. 20 Q. Because of the detrusor instability in time is 11:41. We're going off the record. 29 A. Ves. 20 Q. Bood morning, Dr. Weisberg. How are before, have we not? 29 Q. Because of the detrusor instability in time is 11:45. We're back on the record. 29 Q. Because of the detrusor instability in time i				MR. GAGE: I mean, you know what I'm
A Right. Detrusor instability is another one and that's in the warnings. Q. Doctor, of the adverse reactions of those? In the Writh of those? A Detrusor instability is included in in the warnings and precautions section, not in the warnings and precautions section. MR. BARLOW: Okay. I need to object in the warning again, what we going to go through the whole thing again, what we going to go through the whole thing again, what we going to go through the whole thing again, what we going to go through the whole thing again, what we going to go through the whole thing again, what we going to go through the whole thing again, what we going to go through the whole thing again, what we going to go through the whole thing again, what we going to go through the whole thing again, what we going to go through the whole thing again, what we going to go through the whole thing again, what we going to go through the whole thing again, what we going to go through the whole thing again, what we going to go through the whole thing again, what we going to go through the whole thing again, what we going to go through the whole thing again, what we going to go through the whole thing again, what we going to go through the whole thing again, what we going to go through the whole thing again, what we going to go through the whole thing again, what we going to go through the whole thing again, what we going to g	4		4	
7 another one and that's in the warnings. 8 Q. Doctor, of the adverse reactions 9 listed on 1641, detrusor instability implicates which of those? 11 A. Detrusor instability is included in 12 the IFU in the warnings and precautions section, not 13 in he adverse reactions section. 14 A. Detrusor instability is included in 15 the adverse reactions section. 16 BY MR. BARLOW: Okay. I need to object 17 Q. De novo detrusor instability 18 implicates which, if any, of the urinary adverse 19 reactions listed on 1641 Exhibit 1641? 20 MR. GAGE: He's asking about he's 21 userial might are secured by the se	5	correct?	5	MR. FREESE: I'm going over an IFU.
8		A. Right. Detrusor instability is		
9 stisted on 1641, detrusor instability implicates which of those? 11 A. Detrusor instability is included in 12 to the IFU in the warnings and precautions section, not 13 in the adverse reactions section. 14 MR. BARLOW: Okay. I need to object 15 as nonresponsive. 15 BY MR. BARLOW: 16 BY MR. BARLOW: 16 BY MR. BARLOW: 16 BY MR. BARLOW: 17 Q. De novo detrusor instability 17 Q. De novo detrusor instability 18 implicates which, if any, of the urinary adverse 18 implicates which, if any, of the urinary adverse 18 implicates which, if any, of the urinary adverse 18 implicates which, if any, of the urinary adverse 18 implicates which, if any, of the urinary adverse 18 implicates which, if any, of the urinary adverse 18 implicates which, if any, of the urinary adverse 18 implicates which, if any, of the urinary adverse 18 implicates which, if any, of the urinary adverse 18 implicates which of the urinary adverse 18 implicates which of the urinary one of the urinary adverse 19 portions, perhaps the majority, to review those documents, to come back and seek to question some of the urinary one of the urinary conditions on 19 page 379 pag				
which of those? A. Detrusor instability is included in the IFU in the warnings and precautions section, not in the adverse reactions section. MR. BARLOW: Okay. I need to object the warnings and precautions section. MR. BARLOW: Okay. I need to object the warnings and precautions section. MR. BARLOW: Okay. I need to object the warnings and precautions section. MR. BARLOW: Okay. I need to object the warnings and precautions section. MR. BARLOW: Okay. I need to object the warnings and precautions section. MR. BARLOW: Okay. I need to object the warnings and precautions section. MR. BARLOW: Open own detrusor instability implicates which, if any, of the urinary adverse the warning you to look at this list when you answer the question. THE WITNESS: Oh, I'm sorry. MR. GAGE: So would you now		,		,
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13 in the adverse reactions section. 14 MR. BARLOW: Okay. I need to object a sonoresponsive. 15 as nonresponsive. 16 BY MR. BARLOW: 17 Q. De novo detrusor instability 18 implicates which, if any, of the urinary adverse reactions listed on 1641 Exhibit 1641? 19 reactions listed on 1641 Exhibit 1641? 20 MS. KABBASH: On the list. 21 MR. GAGE: He's asking about he's wanting you to look at this list when you answer the question. 22 question. 23 question. 24 THE WITNESS: Oh, I'm sorry. 25 MR. GAGE: So would you now 26 MR. GAGE: So would you now 27 work that, I'm going to turn it over to Rich. 28 Q. Okay. 29 A. Urge incontinence. 20 Q. Okay. 21 A. Although some patients with detrusor instability in to fret, and then I'm probably going to turn it over to Rich. 20 MR. GAGE: And, Rich, are you please of the detrusor instability? 21 IFUS? 22 IFUS? 23 MR. FREESE: I'm not going over IFUS, and I'm go going to try ou the ad an adequate opportunity to review those decuments. And we reserve our right, after we've had an adequate opportunity to review hose decuments. And we reserve our right, after we've had an adequate opportunity to review those decuments. And we reserve our right, after we've had an adequate opportunity to review those decuments. And we reserve our right, after we've had an adequate opportunity to review those decuments. And we reserve our right, after we've had an adequate opportunity to review those decuments. And we reserve our right, after we've had an adequate opportunity to review those decuments. And we reserve our right, after we've had an adequate opportunity to review those decuments. And we reserve our right, after we've had an adequate opportunity to review those decuments. And we reserve our right, after we've had an adequate opportunity to review those decuments. And we reserve our right, after we've had an adequate opportunity to review those decuments. And we reserve our right, after we've had an adequate opportunity to review those decuments. The time is 11:41. We're going off				
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16 BY MR. BARLOW: Q. De novo detrusor instability miplicates which, if any, of the urinary adverse reactions listed on 1641 - Exhibit 1641? 20 MS. KABBASH: On the list. 21 MR. GAGE: He's asking about - he's wanting you to look at this list when you answer the question. 22 duestion. 23 question. 24 THE WITNESS: Oh, I'm sorry. 25 MR. GAGE: So would you now 26 MR. GAGE: So would you now 27 Page 379 Page 379 Page 379 Page 381 1 THE WITNESS: I misunderstood. MR. GAGE: Alex, reask the question? 3 question? 4 THE WITNESS: Yeah. 5 BY MR. BARLOW: 6 Q. Doctor, detrusor instability 7 implicates which of the urinary conditions on 8 Exhibit 1641? 9 A. Urge incontinence. 9 Q. Doctor, detrusor instability have urinary frequency, also. 11 A. Yes. 12 Q. Okay. 13 A. Although some patients with detrusor 14 instability have urinary frequency, also. 15 Q. Because of the detrusor instability? 16 A. Yes. 17 MR. BARLOW: Doctor, give me just a minute to fret, and then I'm probably going to turn 16 tover to Rich. 27 MR. FREESE: I'm not going over IFUs, 28 I can tell you that. 29 I can tell you that. 20 Jun face deposition, we've been unable to review those decuments. 29 portions, perhaps the majority, of those documents. 20 And we reserve our right, after we've and an adequate opportunity to review those documents, and we reserve our right, after we've and an adequate opportunity to review those documents, and we reserve our right, after we've and deposition, we've been unable to review those documents. 3 And we reserve our right, after we've adocuments, and we reserve our right, after we've adocuments, and an adequate opportunity to review those documents. 4 bad an adequate opportunity to review those documents, and an adequate opportunity to review those documents. 4 bad an adequate opportunity to review those documents. 4 bad an adequate opportunity to review those documents. 4 bad an adequate opportunity to review those documents. 4 bad an adequate opportunity to review those documents. 4 bad an adequate opportunity to		•		
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23 (Pages 378 to 381)

some that you may have already answered and — so in just do your best to work with me, if you don't mind. A. Please proceed. B. Q. Great. Thank you. I want to first show you what is being marked as Plaintiff's Exhibit P-1665. B. E-Mail Chain, ETHLMESH.17619387 through ETH.MESH.17619398, was marked for interpretation of the changes that are the subject of the document, I don't know it pertains at all to the PICU drafts of the changes that are the subject of the deposition. So I don't object to plaintiff's counsel asking him what, if any, relationship this document has to the changes in the IFU, because he may know something that I don't, but I will object to for the changes that are the subject of the deposition. So I don't object to plaintiff's document has to the changes in the IFU, because he may know something that I don't, but I will object to for the changes that are the subject of the deposition. So I don't show it pertains at all to the IFU drafts of the changes that are the subject of the deposition. So I don't object to plaintiff's document has to the changes in the IFU, because he may know something that I don't, but I will object to for the changes that are the subject of the deposition. So I don't object to plaintiff's document has to the changes in the IFU, because he deposition. So I don't know what relationship this has to the IFU and the content has to the changes in the IFU, because he don't know what relationship this has to the IFU. This is a document that was supported the deposition. MR. FREESE: Well, if you need to go to the back to start from the front. Page 383 THE WITNESS: Yeah, yeah. (Pause.) THE WITNESS: Yeah, yeah. (Pause.) THE WITNESS: I have seen them before, but I'll need a few minutes to review all the content. MR. FREESE: Well, if you need some time, we can jump off the record of a cerum, and the process of the scope. A. Let me just take a quick look. MR. FREESE: Well,		Page 382		Page 384
the list of documents that were produced by Ethicon mind. A. Please proceed. Q. Great. Thank you. I want to first show you what is being marked as Plaintiffs' Exhibit P-1665. (Deposition Exhibit No. P-1665, I E-Mail Chain, ETH-MESH.17619387 through FTH-MESH.17619398, was marked for identification.) Yes and the interpretation of the beach of the state of the state of the state of the deposition. By MR. FREESE: Q. And this is a series of e-mails between Stacy Kluesner and Heather Rodriguez and Richard Sedlatschek? Do you see that— Richard Sedlatschek? Do you see that— Sedlatschek Do you see that— Sedlatschek Do you see that— Sedlatschek on you seen these series of e-mails before, Dr. Weisberg? A. Sedlatschek - do you see that— Sed first of all, have you seen these series of e-mails before, Dr. Weisberg? THE WITNESS: Yeah, yeah. (Pause.) THE WITNESS: Yeah, yeah. (Pause.) THE WITNESS: I have seen them before, but I'll need a few minutes to review all the content. MR. FREESE: Well, if you need some time, we can just - we can jump off the record for a second and let you look at it. THE WITNESS: Yeah, just give me five minutes. MR. FREESE: Well, if you need some time, we can just - we can jump off the record or a second and let you look at it. THE WITNESS: Yeah, just give me five minutes. MR. FREESE: Well, if you need some time, we can just - we can jump off the record or a second and let you look at it. THE WITNESS: Yeah, just give me five minutes. MR. FREESE: Well, if you need some time, we can just - we can jump off the record or a second and let you look at it. THE WITNESS: Yeah, just give me five wind you have you shall that the heas seen it and is aware of the document. We're going of the record. MR. GAGE: All fright. The witness and you free questions. MR. GAGE: All fright. The witness and you five questions. MR. GAGE: All fright. The witness and you five questions. MR. GAGE: All fright. The witness and you five questions. MR. GAGE: All oright period. MR. GAGE: All oright period. MR. GAG	1	some that you may have already answered and so	1	Counsel represented that it was on
a mind. A Please proceed. Q Great. Thank you. I want to first show you what is being marked as Plaintiffs' Exhibit P-1665. (Deposition Exhibit No. P-1665. E-Mail Chain, ETH.MESH. 1761938, was marked for identification.) Q Hand this is a series of e-mails between Stacy Kluesner and Heather Rodriguez and Richard Sedlatschek? Do you see that? A Sedlatschek. Q Sedlatschek - do you see that? A Let me just take a quick look. Q Yes, sir. A Let me just take a quick look. MR, GAGE: You need to go to the back to start from the front. Page 383 THE WITNESS: 1 have seen them before, but I'll need a few minutes to review all the content. MR, FREESE: Well, if you need some time, we can just -	2		2	
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24 (Pages 382 to 385)

	Page 386		Page 388
1	document, it's relevant to this deposition and	1	Q. And have done so for many, many
2	within the scope of this deposition.	2	years; correct?
3	MR. GAGE: Got it. So let's go get	3	A. Yes.
4	Marty back in and let's see if he's read it and)	4	Q. And were you aware in December of
5		5	2013 of the e-mail that Jacqueline Ferro from Secant
6	THE VIDEO TECHNICIAN: The time is	6	sent to Lea Ann Conway, Jeff Robertson regarding the
7	11:55. We're back on the record.	7	Secant Medical inquiry on Gynecare mesh products?
8	BY MR. FREESE:	8	A. Although I wasn't involved in this
9	Q. Dr. Weisberg, you have in front of	9	particular issue at the time, I do remember hearing
10	you Plaintiffs' Exhibit 1665; is that correct, sir?	10	about it.
11	A. Yes.	11	Q. Okay. And the issue you heard about
12	Q. And this is a series of e-mails from	12	was that your supplier was concerned about the
13	various people within Ethicon and some folks that	13	complications and alleged injuries occurring from
14	work for a supplier of Ethicon; correct?	14	the use of their Prolene mesh and lawsuits resulting
15 16	A. Yes.	15 16	therefrom; correct? A. That's
17	Q. And you have seen this string of e-mails before?	17	A. That's MR. GAGE: Object to form.
18	A. It looks familiar, but I can't	18	THE WITNESS: That's correct.
19	pinpoint when or how much detail I went into.	19	BY MR. FREESE:
20	Q. Do you remember the last time you saw	20	Q. And wanted Johnson & Johnson to
21	this string of e-mails?	21	answer some questions to satisfy them regarding the
22	A. It was it was no, I don't.	22	concerns that Secant and its insurers had; is that
23	Q. Okay.	23	correct?
24	A. I really don't.	24	A. That's correct.
25	Q. Did you look at it in preparation for	25	Q. Tell me just generally what you
	Page 387		D 200
	rage 307		Page 389
1		1	
1 2	your deposition today? A. I don't believe that I saw this	1 2	remember about the issue, and then I'm going to ask you some specific questions.
	your deposition today?		remember about the issue, and then I'm going to ask
2	your deposition today? A. I don't believe that I saw this	2	remember about the issue, and then I'm going to ask you some specific questions.
2 3 4 5	your deposition today? A. I don't believe that I saw this particular e-mail. Q. You understand, sir, that this document was produced to us as responsive to our	2	remember about the issue, and then I'm going to ask you some specific questions. A. That is pretty much MR. FREESE: Objection; beyond the scope.
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25 (Pages 386 to 389)

	Page 390		Page 392
1	THE WITNESS: That's in my	1	are double-sided. I'm sorry.
2	recollection, it was a discussion that we had, but	2	MR. GAGE: Last page of the e-mail
3		3	chain is what he meant to say.
4	BY MR. FREESE:	4	MR. FREESE: I'm sorry. Last page of
5	Q. When?	5	the e-mail chain. Thank you.
6	A but I I can't pinpoint that.	6	THE WITNESS: Okay.
7	I'm not even sure. This is a fuzzy memory. I knew	7	BY MR. FREESE:
8	that I knew about it. It was a time that Piet was	8	Q. Do you see Ms. Conway's e-mail?
9	managing these things.	9	MR. GAGE: Object to scope.
10	That's the best I can do.	10	THE WITNESS: Yes, I do. Yes, I do.
11	Q. Yes, sir.	11	MR. FREESE: And, William, I'll give
12	Do you recall whether or not anyone	12	you a standing objection on scope on this exhibit if
13	other than Secant in December of 2013 was supplying	13	you want.
14	Johnson & Johnson with Prolene polypropylene mesh	14	MR. GAGE: Yes, I would.
15	for use in TVT products?	15	MR. FREESE: That's fine.
16	A. I don't know the answer to that.	16	MR. GAGE: Is that acceptable to MDL
17	MR. GAGE: Objection; scope.	17	counsel as well?
18	THE WITNESS: I don't know the answer	18	MR. BARLOW: Yes.
19	to that.	19	MR. GAGE: Okay.
20	BY MR. FREESE:	20	BY MR. FREESE:
21	Q. As you sit here today, can you name	21	Q. She goes on first of all, who is
22	me another one other than Secant?	22	Lea Ann Conway?
23	MR. GAGE: Objection; scope.	23	A. I'm trying to think of Lea Ann's
24	THE WITNESS: I cannot.	24	position at that time. I believe she was in our
25	BY MR. FREESE:	25	quality division, but I'm not sure of her particular
	Page 391		Page 393
	1490 371		raye 393
1	Q. You could name Secant, could you not?	1	job.
2	Q. You could name Secant, could you not? MR. GAGE: Objection; scope.	2	job. Q. All right. Have you had occasion to
2	Q. You could name Secant, could you not?MR. GAGE: Objection; scope.THE WITNESS: I knew about Secant.		job. Q. All right. Have you had occasion to work with her?
2 3 4	Q. You could name Secant, could you not? MR. GAGE: Objection; scope. THE WITNESS: I knew about Secant. BY MR. FREESE:	2 3 4	job. Q. All right. Have you had occasion to work with her? A. Yes, and, you know, over the years,
2 3 4 5	Q. You could name Secant, could you not? MR. GAGE: Objection; scope. THE WITNESS: I knew about Secant. BY MR. FREESE: Q. You knew that Secant was a supplier	2 3 4 5	job. Q. All right. Have you had occasion to work with her? A. Yes, and, you know, over the years, people change their you know what? I'm not sure
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	Page 394		Page 396
1	industry our insurance carriers are starting to	1	Q. Essentially, Ms. Ferro's asking for
2	mandate that we no longer sell mesh for device	2	Johnson & Johnson to provide some insight into all
3	applications as outlined under the litigation.	3	the changes that you had made, your company had
4	Do you see that?	4	made, to the IFU user training and protocols to
5	A. Yes.	5	solve or minimize the risk from litigation arising
6	Q. Is that the fact that you became	6	out of the use of Prolene mesh; correct?
7	aware of at some point, through Dr. Hinoul or	7	A. You can get that out of the letter,
8	someone else, that your supplier of Prolene mesh was	8	yes.
9	being instructed by their insurers not to supply	9	Q. All right.
10	Johnson & Johnson with Prolene mesh for use in	10	And the Prolene mesh that she's
11	vaginal and uterine prolapse devices?	11	referring to is the same Prolene mesh that is in all
12	MR. GAGE: Object to form.	12	TVT products; correct?
13	THE WITNESS: Well, pretty much the	13	A. Yes, the mesh is the same.
14	only thing I remember is that that Secant was	14	Q. Now, do you know who and I'm going
15	considering not supplying mesh anymore. That's	15	to mispronounce the name Rick Sedlatschek is?
16	that's pretty much the sum total of this	16	A. Sedlatschek?
17	interaction.	17	Q. Sedlatschek. Thank you.
18	MR. FREESE: Yes, sir.	18	A. Yes.
19	BY MR. FREESE:	19	Q. And he at the time was a vice
20	Q. And it says goes on, quote, There	20	president of quality and regulatory compliance?
21	is also considerable discussion of this at our CEO	21	A. Yes.
22	and board of directors level. It says BOD. Right?	22	Q. Did you work with him?
23	A. Yes.	23	A. On occasion.
24	Q. She goes on to ask, quote, Is it	24	Q. And he prepared a rather lengthy
25	possible for you or a member in your organization to	25	response to Secant to convince Secant to continue to
	Page 395		Page 397
1	share information on the rationale for keeping these	1	sell Prolene mesh to Johnson & Johnson and Ethicon;
2	products on the market? Since the initial launch, I	2	correct?
3	am certain that there has been corrective action for	3	MR. GAGE: Objection to form.
4	complaints and MDRs which resulted in changes to the	4	THE WITNESS: Well, he prepared a
5	IFU, user training, protocols for care after	5	response to answer their questions.
6	implantation, and design changes.	6	BY MR. FREESE:
7	Do you see that?	7	Q. And their question was, what have you
8	A. Yes.	8	done in response to this litigation, because our
9	Q. Are you aware, Dr. Weisberg, whether	9	insurers are telling us they don't want us to sell
10	or not since the initial launch there were any	10	you Prolene mesh anymore for use in your vaginal and
11	changes made by Johnson & Johnson or Ethicon in its	11	pelvic products; correct?
12	IFUs because of lawsuits that were filed against it?	12	MR. GAGE: Object to form.
13	MR. GAGE: Object to form.	13	THE WITNESS: Yes well, they said
14	THE WITNESS: Because of, no.	14	they're starting to tell us.
15	BY MR. FREESE:	15	MR. FREESE: Starting to mandate.
16	Q. Would your answer be, during that	16	THE WITNESS: Starting to mandate,
17	time, there were changes that we've discussed over	17	yeah.
18	the last couple of days?	18	BY MR. FREESE:
19	A. Yes.	19	Q. That they no longer sell mesh to
20	Q. Was there any changes in user	20	Johnson & Johnson.
21	training that Ethicon did since the filing of the	21	A. Right.
22	lawsuits against the company?	22	Q. And this gentleman then writes his
23 24	A. They're constantly updating their	23 24	response to Secant, explaining all of the reasons
25	training. I'm really not sure what changes would have been made when.	25	why Johnson & Johnson believed that it was a safe product; correct?
23	nave seen made when.	23	product, correct:

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	Page 398		Page 400
1	MR. GAGE: Object to form.	1	A. I see it, yes.
2	THE WITNESS: I mean, you said "all	2	Q. Assessing the increased trend in
3	of the reasons." I'm not going to say that this is	3	litigation alleging injuries, do you see that?
4	entirely inclusive of everything that could be said,	4	A. Yes.
5	but I think he responded to their questions.	5	Q. Were you involved in that Quality
6	BY MR. FREESE:	6	Review Board?
7	Q. If you'll look on what's the third	7	A. I was not.
8	page of Mr	8	Q. Who was the most senior medical
9	A. Sedlatschek's?	9	affairs people in December of 2013 involved in that
10	Q. Sedlatschek. Thank you. I'm sorry	10	medical affairs I'm sorry. Let me start over.
11	Mr. Sedlatschek's e-mail, he quotes Dr. Nilsson's	11	Who was the medical affairs doctor
12	17-year follow-up study in support of the safety and	12	involved in the Quality Review Board in December of
13	efficacy of the Prolene mesh?	13	2013?
14	A. Yes.	14	A. I can't tell you for a fact, but it
15	Q. Nowhere does he tell Secant that Dr.	15	was likely Piet Hinoul.
16	Nilsson was a paid consultant for Ethicon, does he?	16	Q. Was there a report prepared out of
17	A. No, not in this letter.	17	that Quality Review Board?
18	Q. He goes on to say that in December of	18	A. Typically, quality review boards do
19	2013, Ethicon conducted a Quality Review Board with	19	publish minutes.
20	its most senior medical affairs, legal, regulatory,	20	Q. Have you looked at those minutes,
21	and quality leaders to assess the increased trend of	21	sir?
22	litigation alleging injuries related to pelvic floor	22	A. I don't believe that I did.
23	repair systems and Gynecare tension-free tape, as	23	Q. And you said you were not part of
24	well as Prolene polypropylene mesh, Mersilene mesh,	24	that Quality Review Board.
25	and UltraPro mesh and hernia repair meshes.	25	A. I was not.
	Page 399		Page 401
1	Do you see that?	1	Q. He goes on to say: In addition to
2	A. Yes, but I have to go back and amend	2	its own analysis, independent professional
3	my last answer.	3	organizations have reaffirmed the safety and
4	Q. Okay.	4	efficacy of polypropylene mesh mid-urethral slings
5	A. Because on the attachment to this	5	such as TVT line of products.
6	letter that Dr. Sedlatschek sent was a paper by	6	And then it goes on to say: For
7	Nilsson, and it said "Conflicts of Interest" on the	7	example, in a 2014 position statement, the American
8	last page. It says, "CGN," which is Nilsson "and CF	8	Urogynecologic Society and the Society of
9	have acted as consultants for Astellas, Ethicon, and	9	Urodynamics that's AUGS and SUFU; correct?
10	Pfizer."	10	A. Yes.
11	Q. All right. And my question to you,	11	Q and he quotes from that position
12	sir, was was, did Mr. Sedlatschek say that in his	12	paper; correct?
13	e-mail?	13	A. Yes.
14	A. No, just in the attachment.	14	Q. And do you see where he calls that an
15	I'm sorry. I lost your last question	15	independent professional organization?
16	entirely.	16	A. Yes.
17	Q. Sure, that's okay. I was asking you	17	Q. Do you know who authored that
18	where he's telling Secant in December of 2013	18	position paper?
19	Ethicon conducted a Quality Review Board.	19	A. I don't recall.
20	A. Okay.	20	Q. Do you know Charles Nager?
21	Q. Do you see that?	21	A. Yes.
22	A. And which page is that?	22	Q. Do you know Dennis Miller?
23	Q. It's right under	23	A. Yes.
24 25	A. I see it.	24	Q. Do you know Eric Rovner?
40	Q the Nilsson comment.	25	A. Yes.

28 (Pages 398 to 401)

	Page 402		Page 404
1	Q. Do you know Paul Tulinkangas?	1	Q. I understand that, but Johnson &
2	A. Not personally.	2	Johnson has very thorough rules and regulations
3	Q. Do you know he was one of the authors	3	governing your investigators to avoid appearance of
4	of the paper?	4	bias, correct, in studies you did clinical trials
5	A. I	5	you did?
6	Q. And do you know Dr. Goldman from	6	A. Well, I mean, we tell it like it is.
7	Cleveland Clinic?	7	You know, if it appears biased and it's not, then
8	A. Yes.	8	it's not biased.
9	Q. Did you know every one of those	9	Q. In fact, Johnson & Johnson doesn't
10	authors first of all, did you know that those	10	allow anymore its investigators of clinical studies
11	were all the authors of the AUGS and SUFU position	11	to have an economic stake in the outcome of the
12 13	paper?	12	data, do they?
14	A. I didn't recall who authored them.	14	A. I don't know that that was the policy in 2013.
15	Q. Well, I'm going to represent to you those are all the authors, and every one of them are	15	Q. Well, I'll represent to you it was
16	paid consultants either to Ethicon, American Medical	16	as of 2010, it was the policy of Johnson & Johnson.
17	Systems, or Boston Scientific Corporation.	17	A. Oh.
18	Did you know that?	18	Q. But my question is, the gentleman
19	A. I was aware that some of them were	19	here on behalf of Ethicon is telling Secant that
20	consultants for us.	20	these are independent professional organizations,
21	Q. Well some were consultants for	21	but he does not tell him or tell Secant that the
22	you, but every one of them were consultants for	22	authors of these position papers are all paid-for
23	either you or your competitors.	23	consultants by industry, does he?
24	MR. GAGE: Object to form.	24	MR. GAGE: Object to form.
25	BY MR. FREESE:	25	THE WITNESS: No, that's not in
	D 400		
	Page 403		Page 405
1	Q. Did you know that?	1	there.
2		1 2	
2	Q. Did you know that?A. I wasn't sure of that, no.Q. It doesn't make them very	1	there. BY MR. FREESE: Q. And as you sit here today, you've not
2 3 4	Q. Did you know that?A. I wasn't sure of that, no.Q. It doesn't make them very independent, does it?	2 3 4	there. BY MR. FREESE: Q. And as you sit here today, you've not reviewed any of the results of that Quality Review
2 3 4 5	Q. Did you know that? A. I wasn't sure of that, no. Q. It doesn't make them very independent, does it? MR. GAGE: Object to form.	2 3 4 5	there. BY MR. FREESE: Q. And as you sit here today, you've not reviewed any of the results of that Quality Review Board.
2 3 4 5 6	Q. Did you know that? A. I wasn't sure of that, no. Q. It doesn't make them very independent, does it? MR. GAGE: Object to form. THE WITNESS: Pardon me?	2 3 4 5 6	there. BY MR. FREESE: Q. And as you sit here today, you've not reviewed any of the results of that Quality Review Board. A. If I did, I don't recall.
2 3 4 5 6 7	Q. Did you know that? A. I wasn't sure of that, no. Q. It doesn't make them very independent, does it? MR. GAGE: Object to form. THE WITNESS: Pardon me? MR. GAGE: No	2 3 4 5 6 7	there. BY MR. FREESE: Q. And as you sit here today, you've not reviewed any of the results of that Quality Review Board. A. If I did, I don't recall. Q. Now, if you'll look up to the next
2 3 4 5 6 7 8	Q. Did you know that? A. I wasn't sure of that, no. Q. It doesn't make them very independent, does it? MR. GAGE: Object to form. THE WITNESS: Pardon me? MR. GAGE: No THE WITNESS: Oh. I think that these	2 3 4 5 6 7 8	there. BY MR. FREESE: Q. And as you sit here today, you've not reviewed any of the results of that Quality Review Board. A. If I did, I don't recall. Q. Now, if you'll look up to the next e-mail above that
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2 3 4 5 6 7 8 9	Q. Did you know that? A. I wasn't sure of that, no. Q. It doesn't make them very independent, does it? MR. GAGE: Object to form. THE WITNESS: Pardon me? MR. GAGE: No THE WITNESS: Oh. I think that these are ethical people who gave ethical answers based on their clinical experience, and they're honest and	2 3 4 5 6 7 8 9	there. BY MR. FREESE: Q. And as you sit here today, you've not reviewed any of the results of that Quality Review Board. A. If I did, I don't recall. Q. Now, if you'll look up to the next e-mail above that A. Date, please? Q. Yes, March 26th, 2014
2 3 4 5 6 7 8 9 10	Q. Did you know that? A. I wasn't sure of that, no. Q. It doesn't make them very independent, does it? MR. GAGE: Object to form. THE WITNESS: Pardon me? MR. GAGE: No THE WITNESS: Oh. I think that these are ethical people who gave ethical answers based on their clinical experience, and they're honest and the organizations that they work for are concerned	2 3 4 5 6 7 8 9 10	there. BY MR. FREESE: Q. And as you sit here today, you've not reviewed any of the results of that Quality Review Board. A. If I did, I don't recall. Q. Now, if you'll look up to the next e-mail above that A. Date, please? Q. Yes, March 26th, 2014 A. Okay.
2 3 4 5 6 7 8 9 10 11	Q. Did you know that? A. I wasn't sure of that, no. Q. It doesn't make them very independent, does it? MR. GAGE: Object to form. THE WITNESS: Pardon me? MR. GAGE: No THE WITNESS: Oh. I think that these are ethical people who gave ethical answers based on their clinical experience, and they're honest and the organizations that they work for are concerned about women's health.	2 3 4 5 6 7 8 9 10 11	there. BY MR. FREESE: Q. And as you sit here today, you've not reviewed any of the results of that Quality Review Board. A. If I did, I don't recall. Q. Now, if you'll look up to the next e-mail above that A. Date, please? Q. Yes, March 26th, 2014 A. Okay. Q written to Adrienne Brott do
2 3 4 5 6 7 8 9 10 11 12 13	Q. Did you know that? A. I wasn't sure of that, no. Q. It doesn't make them very independent, does it? MR. GAGE: Object to form. THE WITNESS: Pardon me? MR. GAGE: No THE WITNESS: Oh. I think that these are ethical people who gave ethical answers based on their clinical experience, and they're honest and the organizations that they work for are concerned about women's health. MR. FREESE: Move to strike.	2 3 4 5 6 7 8 9 10 11 12	there. BY MR. FREESE: Q. And as you sit here today, you've not reviewed any of the results of that Quality Review Board. A. If I did, I don't recall. Q. Now, if you'll look up to the next e-mail above that A. Date, please? Q. Yes, March 26th, 2014 A. Okay. Q written to Adrienne Brott do you know her?
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	Q. Did you know that? A. I wasn't sure of that, no. Q. It doesn't make them very independent, does it? MR. GAGE: Object to form. THE WITNESS: Pardon me? MR. GAGE: No THE WITNESS: Oh. I think that these are ethical people who gave ethical answers based on their clinical experience, and they're honest and the organizations that they work for are concerned about women's health. MR. FREESE: Move to strike. Doctor, that really wasn't my question. BY MR. FREESE:	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	there. BY MR. FREESE: Q. And as you sit here today, you've not reviewed any of the results of that Quality Review Board. A. If I did, I don't recall. Q. Now, if you'll look up to the next e-mail above that A. Date, please? Q. Yes, March 26th, 2014 A. Okay. Q written to Adrienne Brott do you know her? A. Not yes, I know who she is. Q. And who is she? A. See I believe she was she was
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. Did you know that? A. I wasn't sure of that, no. Q. It doesn't make them very independent, does it? MR. GAGE: Object to form. THE WITNESS: Pardon me? MR. GAGE: No THE WITNESS: Oh. I think that these are ethical people who gave ethical answers based on their clinical experience, and they're honest and the organizations that they work for are concerned about women's health. MR. FREESE: Move to strike. Doctor, that really wasn't my question. BY MR. FREESE: Q. As paid consultants for Ethicon and Boston Scientific Corporation and American Medical Systems, there might be an appearance of bias if they are writing position papers saying that the industries that they're being paid by are making	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	there. BY MR. FREESE: Q. And as you sit here today, you've not reviewed any of the results of that Quality Review Board. A. If I did, I don't recall. Q. Now, if you'll look up to the next e-mail above that A. Date, please? Q. Yes, March 26th, 2014 A. Okay. Q written to Adrienne Brott do you know her? A. Not yes, I know who she is. Q. And who is she? A. See I believe she was she was with quality, too, but I'm not sure. Q. And Mr. Sedlatschek writes: The outline below is a response I had sent to Secant Medical in response to their request. I recommend
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q. Did you know that? A. I wasn't sure of that, no. Q. It doesn't make them very independent, does it? MR. GAGE: Object to form. THE WITNESS: Pardon me? MR. GAGE: No THE WITNESS: Oh. I think that these are ethical people who gave ethical answers based on their clinical experience, and they're honest and the organizations that they work for are concerned about women's health. MR. FREESE: Move to strike. Doctor, that really wasn't my question. BY MR. FREESE: Q. As paid consultants for Ethicon and Boston Scientific Corporation and American Medical Systems, there might be an appearance of bias if they are writing position papers saying that the industries that they're being paid by are making products that are safe and effective. You'd agree with me?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	there. BY MR. FREESE: Q. And as you sit here today, you've not reviewed any of the results of that Quality Review Board. A. If I did, I don't recall. Q. Now, if you'll look up to the next e-mail above that A. Date, please? Q. Yes, March 26th, 2014 A. Okay. Q written to Adrienne Brott do you know her? A. Not yes, I know who she is. Q. And who is she? A. See I believe she was she was with quality, too, but I'm not sure. Q. And Mr. Sedlatschek writes: The outline below is a response I had sent to Secant Medical in response to their request. I recommend you leverage it as much as possible in support of our response to Health Canada regarding similar questions and concerns. This info was reviewed and

29 (Pages 402 to 405)

	Page 406		Page 408
1	Do you see that?	1	any of the Health Canada meetings. This may have
2	A. Yes.	2	been a behind-the-scenes, you know, somebody's
3	Q. What does that mean?	3	working to get an answer to this question. They may
4	A. It means that it's accurate.	4	have pulled it out of there. They may have pulled
5	Q. What does it mean to leverage as much	5	it out of, you know, any previous vetted, accurate
6	as possible in support of our response to Health	6	answers.
7	Canada?	7	Q. Did you did you vet any of the
8	A. Well, Mr. Sedlatschek put a lot of	8	responses that went to Health Canada, sir?
9	work into that and has a lot of statistics and a lot	9	A. They were all vetted.
10	of facts that are in there; and rather than	10	Q. By you?
11	reinventing the wheel, if the questions are the	11	A. Yes.
12	same, we know that we have a well-vetted document	12	Q. And who else?
13	from which we can take information without having to		A. Oh, I suspect that well, I can
14	go back to the files.	14	tell you the team, because everybody looked at them,
15	Q. And he was telling Ms. Brott to use	15	and I think I have a list of the Health Canada team.
16	this information that he sent to Secant in	16	These are just
17	leveraging their response to Health Canada.	17	(Pause.)
18	MR. GAGE: Object to form.	18	THE WITNESS: Do I have a list of the
19	THE WITNESS: Well, as I said, I am	19	Health Canada team. I have a list of the people who
20	interpreting leveraging the way I think it was	20	participated in changing of the IFU, but I don't
21	intended, and that means that here are answers that	21	have a list of the people on the Health Canada team.
22	we researched and validated, use these to answer any	22	MR. FREESE: Let's go ahead and mark
23	other questions that Secant may ask.	23	that as an exhibit so we'll have that.
24	MR. FREESE: That's my question.	24	THE WITNESS: Okay.
25	BY MR. FREESE:	25	MR. FREESE: Has it already been
	Page 407		Page 409
1	Q. He's telling her to use this Secant	1	marked or
2	response in responding to Health Canada if they ask	2	MR. KABBASH: No.
3	similar questions	3	MR. GAGE: No.
4	A. Yes.	4	MR. FREESE: I'm sure Mr. Gage won't
5	Q about the product; correct?	5	mind. He's probably got a thousand of these sitting
6	A. Yes.	6	around somewhere.
7	Q. And you were involved in the Health	7	around somewhere.
8	Canada project, were you not?	8	(Deposition Exhibit No. P-1666,
9	A. I was.	9	Document Labeled "Ethicon Approvers of
10	Q. That's why you're the spokesman for	10	2015 Pelvic Mesh IFU Changes", was marked
11	the company today; correct?	11	for identification.)
12	MR. GAGE: Object to form.	12	ior identification.)
13	THE WITNESS: I don't know the second	13	BY MR. FREESE:
14	answer, but the first answer is, yes, I was involved	14	Q. And P-1666 is entitled "Ethicon
15	in it.	15	Approvers of 2015 Pelvic Mesh IFU Changes"?
16	MR. FREESE: And you know you're here	16	A. Yes.
17	today to speak on behalf of the corporation on the	17	Q. You're obviously on there; correct?
′	Health Canada issues; correct?	18	A. Yes.
18	Tionidi Culludu 155005, COlloct.	19	Q. Stacy Kluesner in regulatory affairs
18 19	THE WITNESS: Yes	1 ユラ	
19	THE WITNESS: Yes. BY MR FREESE:		
19 20	BY MR. FREESE:	20	is on there; correct?
19 20 21	BY MR. FREESE: Q. And here's a document that is being	20 21	is on there; correct? A. Yes.
19 20 21 22	BY MR. FREESE: Q. And here's a document that is being recommended to use in the Health Canada response.	20 21 22	is on there; correct? A. Yes. Q. And, in fact, she's on the e-mail
19 20 21 22 23	BY MR. FREESE: Q. And here's a document that is being recommended to use in the Health Canada response. A. Yes.	20 21 22 23	is on there; correct? A. Yes. Q. And, in fact, she's on the e-mail chain with Sedlatschek and Brott over this Secant
19 20 21 22	BY MR. FREESE: Q. And here's a document that is being recommended to use in the Health Canada response.	20 21 22	is on there; correct? A. Yes. Q. And, in fact, she's on the e-mail

30 (Pages 406 to 409)

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Page 412
                                              Page 410
1
               And you said there was a Health
                                                            1
                                                                of those individuals. I believe they might have
2
                                                            2
     Canada team -- was that a distinct group of people
                                                                been discussed with Adam yesterday.
                                                            3
3
                                                                         MR. FREESE: Okay.
     known as the Health Canada team?
4
               Yeah, and many of those -- them may
                                                            4
                                                                         MS. KABBASH: But I don't know that
5
     be on that list, but the -- there was -- there were
                                                            5
                                                                we have seen minutes beyond those Quality Review
6
     Health Canada meetings on a regular basis from the
                                                            6
                                                                Board meeting --
7
     time we got the initial letter until the time that
                                                            7
                                                                         MR. GAGE: It may be there.
8
                                                            8
     Health Canada said that the situation was resolved.
                                                                         MS. KABBASH: They may be there --
9
              Closed, I think, was their words.
                                                            9
                                                                         MR. GAGE: But we just haven't seen
10
         Q.
               And --
                                                           10
                                                                them.
                                                           11
11
         A.
               Now, I'm -- let me back that off.
                                                                         MR. FREESE: Do you have an exemplar
     That may have been the FDA that said it was closed.
12
                                                           12
13
              There was a Health Canada team that
                                                           13
                                                                         THE WITNESS: I don't. I mean, my
14
     started when we got the initial letter until we
                                                           14
                                                                computer was swept, so every meeting invitation that
     submitted our response and then for a little bit
15
                                                           15
                                                                said Health Canada on it was pulled and provided.
                                                                         MR. FREESE: Okay.
16
     after that.
                                                           16
17
               And it may have included more than
                                                           17
                                                                BY MR. FREESE:
         Q.
18
     what's on Exhibit 1666?
                                                           18
                                                                          Dr. Weisberg, you said all the
19
               That's correct.
                                                           19
                                                                communications with Health Canada were thoroughly
         A.
                                                           20
20
               Do you believe there's a document
                                                                vetted by yourself and other members of the Health
         O.
21
     somewhere identifying everyone who's on the Health
                                                           21
                                                                Canada team?
22
     Canada team?
                                                           22
                                                                    A.
                                                                          Yes.
               I'm sure there is.
                                                           23
23
                                                                    O.
                                                                          Did anybody tell Health Canada that
         A.
               You just don't have it with you --
                                                                your possibly sole supplier of polypropylene mesh
24
         Q.
                                                           24
               I just didn't pull that out. I
                                                                was threatening to stop selling it to you because it
25
         A.
                                                           25
                                              Page 411
1
     pulled out a couple of things that I knew I wouldn't
                                                            1
                                                                was concerned about safety matters and the use of
                                                            2
2
     remember, lists of people, and that just wasn't a
                                                                its products for permanent implantation in women?
                                                            3
3
     list of the people.
                                                                         MR. GAGE: Object to form.
                                                                         THE WITNESS: I don't believe so.
                                                            4
4
               But it is a discrete document you
         O.
    looked at in preparation for your deposition.
                                                            5
5
                                                                BY MR. FREESE:
6
               No, but I looked at a series of
                                                            6
                                                                        Did you ever suggest that might be a
7
     e-mails and minutes from -- from the Health Canada
                                                            7
                                                                prudent thing to do?
                                                            8
8
     team meetings and if you look up at the top, you can
                                                                          That's something that our regulatory
9
     see who is addressed and those would be the people.
                                                            9
                                                                and legal people would probably address better than
10
              MR. FREESE: I don't know if we have
                                                           10
                                                                I.
     seen those yet. I don't have the Health Canada
                                                           11
                                                                          And as you sit here today, you know
11
                                                                    0.
                                                                that nobody in regulatory alerted Health Canada
12
     minute meetings, not to say they're not in the
                                                           12
13
     300,000 pages that were produced --
                                                           13
                                                                during this whole IFU discussion with Health Canada
14
              MR. GAGE: They're in there.
                                                           14
                                                                that your either major or sole supplier of
15
              THE WITNESS: Even in the meeting
                                                           15
                                                                polypropylene mesh was threatening to -- refusing to
     invitations, their names would be in there.
                                                           16
                                                                even sell you the product anymore because of safety
16
              MR. FREESE: Oh, that's fine.
                                                           17
17
                                                                concerns; correct?
                                                           18
18
              MR. GAGE: Hang on a second, Rich.
                                                                         MR. GAGE: Object to form.
                                                           19
                                                                         THE WITNESS: I'm not aware of that.
19
              (Pause.)
20
              MR. GAGE: Rich, let Maha --
                                                           20
                                                                BY MR. FREESE:
21
              MS. KABBASH: The only minutes that
                                                           21
                                                                          Do you believe that that would have
    I'm aware of that exist, Rich -- I'm not going to
                                                           22
                                                                been a prudent piece of information that Health
22
                                                                Canada might have considered relevant in its
     say none exist, but what we have seen is the minutes
                                                           23
23
24
     from the Quality Review Board meetings held in June
                                                           24
                                                                assessment of your IFU?
     and August 2014. And Dr. Weisberg does have a list
                                                           25
                                                                         MR. GAGE: Object to form.
25
```

31 (Pages 410 to 413)

Page 414 Page 416 1 THE WITNESS: Well, I think if they 1 Could you answer my question? I can 2 2 have the court reporter read it back if you need to. stopped selling it to us, that it would be prudent; 3 but they wanted to discuss with us about whether to 3 I -- I don't know where the line 4 sell it to us or not, I don't know that that's --4 stops about what needed to be transmitted to them 5 that would be prudent. 5 and what didn't and --6 6 BY MR. FREESE: Well, let's break it down then. Did 7 7 all of your responses to Health Canada need to be Okay. Well, how about if the reason O. 8 8 they were discussing refusing to sell it to you was fully truthful and open and honest? 9 because of fears of injuries that were being caused 9 A. Yes. 10 by women using the product? 10 And the supplier of your Q. MR. GAGE: Object to form. 11 11 polypropylene mesh was questioning whether or not BY MR. FREESE: they should even continue to sell you the mesh 12 12 13 Do you think that would have been a 13 anymore; correct? relevant piece of information to share with the 14 14 A. No, they were alerting us that they 15 officials at Health Canada? 15 may be mandated to not sell it to us, may be. 16 MR. GAGE: Object to form. 16 And if they stopped selling you mesh, 17 THE WITNESS: No. I think that once 17 that would have necessitated you stop making your 18 a result was -- was -- once there was a conclusion 18 slings; correct? MR. GAGE: Object to form. 19 to their inquiries, then it may have been important 19 20 20 THE WITNESS: I'm not familiar enough to tell them. 21 BY MR. FREESE: 21 with our operations people to know whether they had 22 It may have been important to tell 22 another supplier. 23 BY MR. FREESE: 23 Health Canada. 24 24 Α. Yes. Well, can we agree that Secant refusing to sell you polypropylene mesh would have 25 O. But they never got told, did they? 25 Page 415 Page 417 1 A. Well, that's because there was no 1 been a major disruption to your manufacturing 2 change in what was being supplied to us. 2 process? 3 3 Well, they couldn't comment on MR. GAGE: Object to form. 4 something they weren't told and they didn't know, 4 THE WITNESS: If that happened, which 5 5 could they? it didn't. 6 MR. GAGE: Object to form. 6 MR. FREESE: I understand. 7 THE WITNESS: This question is -- is 7 BY MR. FREESE: 8 8 strictly a legal and regulatory question; and And during that time that you were 9 although I am representing the company, I was not 9 dealing with Health Canada, you had already been in 10 involved in any discussions about whether or not to 10 discussions for many months with Secant where they 11 include that information. 11 were expressing the concern over the safety of the 12 12 BY MR. FREESE: use of mesh in vaginal and pelvic floor products; 13 13 Well, but you were on the team that correct? 14 was vetting all the information that was going to 14 MR. GAGE: Object to form. 15 Health Canada; correct? 15 THE WITNESS: Yes. 16 A. We vetted the information that was --16 BY MR. FREESE: 17 17 that we drafted. And someone at Ethicon made the 18 18 You wanted to give Health Canada a decision not to share that information with Health full and complete and honest appraisal of the 19 19 Canada: correct? 20 situation as it existed in 2014 when you were having 20 MR. GAGE: Object to form. THE WITNESS: I don't know if it was 21 these discussions with Health Canada; correct? 2.1 22 MR. GAGE: Object to form. 22 even brought up and a decision was made or it was THE WITNESS: We needed to answer just considered nothing that we needed to consider. 23 23 24 Health Canada's questions. 24 BY MR. FREESE: BY MR. FREESE: 25 25 You certainly did not suggest telling

32 (Pages 414 to 417)

	Page 418		Page 420
1	Health Canada about what Secant was threatening to	1	Q the subject is Health Canada?
2	do; correct?	2	A. Yes.
3	MR. GAGE: Objection.	3	Q as per our discussion, could
4	THE WITNESS: They didn't threaten	4	medical please help to create a response to: In
5	anything. They informed us.	5	addition, one or more revision surgeries may be
6	BY MR. FREESE:	6	necessary to treat these complications, while some
7	Q. You did not inform Health Canada that	7	complications may not always be completely
8	Secant was alerting you that they were being	8	corrected.
9	mandated not to sell you polypropylene mesh anymore;	9	Do you see that?
10	correct?	10	A. Yes.
11	A. We did not.	11	Q. And that was one of the questions
12	Q. And to your knowledge, no one else at	12	posed by Health Canada; correct?
13	Ethicon, either in regulatory affairs or marketing	13	A. Yes.
14	or compliance or global supply or legal, no one	14	Q. And Ms. Kluesner was looking on how
15	suggested telling Health Canada about the Secant	15	to respond to that; correct?
16	issue; correct?	16	A. Yes.
17	MR. GAGE: Object to form.	17	Q. And she came to you for that;
18	THE WITNESS: That's correct.	18	correct?
19	BY MR. FREESE:	19	A. Yes, she did.
20	Q. Do you know or have you seen what	20	Q. And she said: Points we discussed
21	Secant's response was to Mr. Sedlatschek's e-mail?	21	during our meeting and I assume that's a meeting
22	A. I don't believe I did.	22	that you were in?
23	Q. As you sit here today, Dr. Weisberg,	23	A. Likely.
24	do you know if there even was a response to it?	24	Q. One of your Health Canada meetings?
25	A. I don't know.	25	A. I suspect.
	Page 419		Page 421
1	Q. Is he still with the company?	1	Q it says, the need for the revision
1 2	Q. Is he still with the company?A. I believe he is.	1 2	
			Q it says, the need for the revision
2	A. I believe he is.	2	Q it says, the need for the revision surgery is independent of the mesh.
2	A. I believe he is.Q. Is he still in this same job?	2	Q it says, the need for the revision surgery is independent of the mesh. A. Yes.
2 3 4	A. I believe he is.Q. Is he still in this same job?A. Yes.	2 3 4	Q it says, the need for the revision surgery is independent of the mesh. A. Yes. Q. The mesh is fine, does not fail.
2 3 4 5	A. I believe he is.Q. Is he still in this same job?A. Yes.Q. Does he work here in Somerville?	2 3 4 5	Q it says, the need for the revision surgery is independent of the mesh. A. Yes. Q. The mesh is fine, does not fail. A. Yes.
2 3 4 5 6	 A. I believe he is. Q. Is he still in this same job? A. Yes. Q. Does he work here in Somerville? A. I don't know whether he's in 	2 3 4 5 6	Q it says, the need for the revision surgery is independent of the mesh. A. Yes. Q. The mesh is fine, does not fail. A. Yes. Q. In these cases, the tissue's what
2 3 4 5 6 7	 A. I believe he is. Q. Is he still in this same job? A. Yes. Q. Does he work here in Somerville? A. I don't know whether he's in Somerville or in Cincinnati, or in New Brunswick for that matter. MR. FREESE: All right, Dr. Weisberg. 	2 3 4 5 6 7	Q it says, the need for the revision surgery is independent of the mesh. A. Yes. Q. The mesh is fine, does not fail. A. Yes. Q. In these cases, the tissue's what fails, do you see that?
2 3 4 5 6 7 8	 A. I believe he is. Q. Is he still in this same job? A. Yes. Q. Does he work here in Somerville? A. I don't know whether he's in Somerville or in Cincinnati, or in New Brunswick for that matter. 	2 3 4 5 6 7 8	Q it says, the need for the revision surgery is independent of the mesh. A. Yes. Q. The mesh is fine, does not fail. A. Yes. Q. In these cases, the tissue's what fails, do you see that? A. Yes.
2 3 4 5 6 7 8	 A. I believe he is. Q. Is he still in this same job? A. Yes. Q. Does he work here in Somerville? A. I don't know whether he's in Somerville or in Cincinnati, or in New Brunswick for that matter. MR. FREESE: All right, Dr. Weisberg. 	2 3 4 5 6 7 8	Q it says, the need for the revision surgery is independent of the mesh. A. Yes. Q. The mesh is fine, does not fail. A. Yes. Q. In these cases, the tissue's what fails, do you see that? A. Yes. Q. Who came up with those points, those
2 3 4 5 6 7 8 9	 A. I believe he is. Q. Is he still in this same job? A. Yes. Q. Does he work here in Somerville? A. I don't know whether he's in Somerville or in Cincinnati, or in New Brunswick for that matter. MR. FREESE: All right, Dr. Weisberg. I'm going to show you what I'm marking as Exhibit 	2 3 4 5 6 7 8 9	Q it says, the need for the revision surgery is independent of the mesh. A. Yes. Q. The mesh is fine, does not fail. A. Yes. Q. In these cases, the tissue's what fails, do you see that? A. Yes. Q. Who came up with those points, those bullet points?
2 3 4 5 6 7 8 9 10 11 12 13	 A. I believe he is. Q. Is he still in this same job? A. Yes. Q. Does he work here in Somerville? A. I don't know whether he's in Somerville or in Cincinnati, or in New Brunswick for that matter. MR. FREESE: All right, Dr. Weisberg. I'm going to show you what I'm marking as Exhibit 	2 3 4 5 6 7 8 9 10	Q it says, the need for the revision surgery is independent of the mesh. A. Yes. Q. The mesh is fine, does not fail. A. Yes. Q. In these cases, the tissue's what fails, do you see that? A. Yes. Q. Who came up with those points, those bullet points? A. They were discussed at the meeting
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	A. I believe he is. Q. Is he still in this same job? A. Yes. Q. Does he work here in Somerville? A. I don't know whether he's in Somerville or in Cincinnati, or in New Brunswick for that matter. MR. FREESE: All right, Dr. Weisberg. I'm going to show you what I'm marking as Exhibit 1667. (Deposition Exhibit No. P-1667, 4/14 E-Mail Chain, ETH.MESH.176324274 and	2 3 4 5 6 7 8 9 10 11 12 13 14	Q it says, the need for the revision surgery is independent of the mesh. A. Yes. Q. The mesh is fine, does not fail. A. Yes. Q. In these cases, the tissue's what fails, do you see that? A. Yes. Q. Who came up with those points, those bullet points? A. They were discussed at the meeting and it was explained that when these operations fail, it's not because the mesh rips or comes apart or absorbs or goes away.
2 3 4 5 6 7 8 9 10 11 12 13 14 15	A. I believe he is. Q. Is he still in this same job? A. Yes. Q. Does he work here in Somerville? A. I don't know whether he's in Somerville or in Cincinnati, or in New Brunswick for that matter. MR. FREESE: All right, Dr. Weisberg. I'm going to show you what I'm marking as Exhibit 1667. (Deposition Exhibit No. P-1667, 4/14 E-Mail Chain, ETH.MESH.176324274 and ETH.MESH.176324275, was marked for identification.)	2 3 4 5 6 7 8 9 10 11 12 13 14 15	Q it says, the need for the revision surgery is independent of the mesh. A. Yes. Q. The mesh is fine, does not fail. A. Yes. Q. In these cases, the tissue's what fails, do you see that? A. Yes. Q. Who came up with those points, those bullet points? A. They were discussed at the meeting and it was explained that when these operations fail, it's not because the mesh rips or comes apart or absorbs or goes away. It's because what it's attached to, the tissue it's attached to, it may pull pull loose or a part of the pelvic floor that's not
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. I believe he is. Q. Is he still in this same job? A. Yes. Q. Does he work here in Somerville? A. I don't know whether he's in Somerville or in Cincinnati, or in New Brunswick for that matter. MR. FREESE: All right, Dr. Weisberg. I'm going to show you what I'm marking as Exhibit 1667. (Deposition Exhibit No. P-1667, 4/14 E-Mail Chain, ETH.MESH.176324274 and ETH.MESH.176324275, was marked for	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	Q it says, the need for the revision surgery is independent of the mesh. A. Yes. Q. The mesh is fine, does not fail. A. Yes. Q. In these cases, the tissue's what fails, do you see that? A. Yes. Q. Who came up with those points, those bullet points? A. They were discussed at the meeting and it was explained that when these operations fail, it's not because the mesh rips or comes apart or absorbs or goes away. It's because what it's attached to, the tissue it's attached to, it may pull pull loose or a part of the pelvic floor that's not covered by the mesh may create a new recurrence.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	A. I believe he is. Q. Is he still in this same job? A. Yes. Q. Does he work here in Somerville? A. I don't know whether he's in Somerville or in Cincinnati, or in New Brunswick for that matter. MR. FREESE: All right, Dr. Weisberg. I'm going to show you what I'm marking as Exhibit 1667. (Deposition Exhibit No. P-1667, 4/14 E-Mail Chain, ETH.MESH.176324274 and ETH.MESH.176324275, was marked for identification.)	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	Q it says, the need for the revision surgery is independent of the mesh. A. Yes. Q. The mesh is fine, does not fail. A. Yes. Q. In these cases, the tissue's what fails, do you see that? A. Yes. Q. Who came up with those points, those bullet points? A. They were discussed at the meeting and it was explained that when these operations fail, it's not because the mesh rips or comes apart or absorbs or goes away. It's because what it's attached to, the tissue it's attached to, it may pull pull loose or a part of the pelvic floor that's not covered by the mesh may create a new recurrence. Q. Well, can we agree that whatever
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. I believe he is. Q. Is he still in this same job? A. Yes. Q. Does he work here in Somerville? A. I don't know whether he's in Somerville or in Cincinnati, or in New Brunswick for that matter. MR. FREESE: All right, Dr. Weisberg. I'm going to show you what I'm marking as Exhibit 1667. (Deposition Exhibit No. P-1667, 4/14 E-Mail Chain, ETH.MESH.176324274 and ETH.MESH.176324275, was marked for identification.) BY MR. FREESE: Q. I assume you've seen this document before, sir? A. Yes.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q it says, the need for the revision surgery is independent of the mesh. A. Yes. Q. The mesh is fine, does not fail. A. Yes. Q. In these cases, the tissue's what fails, do you see that? A. Yes. Q. Who came up with those points, those bullet points? A. They were discussed at the meeting and it was explained that when these operations fail, it's not because the mesh rips or comes apart or absorbs or goes away. It's because what it's attached to, the tissue it's attached to, it may pull pull loose or a part of the pelvic floor that's not covered by the mesh may create a new recurrence. Q. Well, can we agree that whatever surgery for revision is necessary is because of the implantation of the mesh; correct? If the mesh
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	A. I believe he is. Q. Is he still in this same job? A. Yes. Q. Does he work here in Somerville? A. I don't know whether he's in Somerville or in Cincinnati, or in New Brunswick for that matter. MR. FREESE: All right, Dr. Weisberg. I'm going to show you what I'm marking as Exhibit 1667. (Deposition Exhibit No. P-1667, 4/14 E-Mail Chain, ETH.MESH.176324274 and ETH.MESH.176324275, was marked for identification.) BY MR. FREESE: Q. I assume you've seen this document before, sir? A. Yes. Q. Stacy Kluesner writes you in April of	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q it says, the need for the revision surgery is independent of the mesh. A. Yes. Q. The mesh is fine, does not fail. A. Yes. Q. In these cases, the tissue's what fails, do you see that? A. Yes. Q. Who came up with those points, those bullet points? A. They were discussed at the meeting and it was explained that when these operations fail, it's not because the mesh rips or comes apart or absorbs or goes away. It's because what it's attached to, the tissue it's attached to, it may pull pull loose or a part of the pelvic floor that's not covered by the mesh may create a new recurrence. Q. Well, can we agree that whatever surgery for revision is necessary is because of the implantation of the mesh; correct? If the mesh wasn't there, you wouldn't need a revision surgery,
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. I believe he is. Q. Is he still in this same job? A. Yes. Q. Does he work here in Somerville? A. I don't know whether he's in Somerville or in Cincinnati, or in New Brunswick for that matter. MR. FREESE: All right, Dr. Weisberg. I'm going to show you what I'm marking as Exhibit 1667. (Deposition Exhibit No. P-1667, 4/14 E-Mail Chain, ETH.MESH.176324274 and ETH.MESH.176324275, was marked for identification.) BY MR. FREESE: Q. I assume you've seen this document before, sir? A. Yes. Q. Stacy Kluesner writes you in April of 2014 and says, quote, Hi, Marty that's you;	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q it says, the need for the revision surgery is independent of the mesh. A. Yes. Q. The mesh is fine, does not fail. A. Yes. Q. In these cases, the tissue's what fails, do you see that? A. Yes. Q. Who came up with those points, those bullet points? A. They were discussed at the meeting and it was explained that when these operations fail, it's not because the mesh rips or comes apart or absorbs or goes away. It's because what it's attached to, the tissue it's attached to, it may pull pull loose or a part of the pelvic floor that's not covered by the mesh may create a new recurrence. Q. Well, can we agree that whatever surgery for revision is necessary is because of the implantation of the mesh; correct? If the mesh wasn't there, you wouldn't need a revision surgery, would you?

33 (Pages 418 to 421)

	Page 422		Page 424
1	example I can give you is that now, let's see	1	Q. So at least in that respect, that is
2	what device we're talking about. Anything okay.	2	not a totally accurate statement, is it, that the
3	If somebody does an anterior repair	3	need for revision surgery is independent of the
4	of pelvic floor prolapse and somebody has another	4	mesh?
5	prolapse, which is from the top of the vagina or the	5	A. Well, I'm not sure that I made that
6	bottom of the vagina, that's really due to the	6	statement. This is what Stacy said that her
7	tissue that's bad and you've fixed one part and the	7	interpretation of what the results of the meeting
8	other parts didn't get fixed, and that sometimes	8	were.
9	happens, especially if you reinforce one part,	9	Q. I understand. These are not your
10	another part may pop through.	10	words. So you do not agree that the literal things
11	Q. In fact, that was an identified	11	she wrote there is correct, do you?
12	complication of Prosima, was it not?	12	A. I agree in yeah, I do agree with
13	A. Yes.	13	them. The mesh is generally fine and the mesh
14	Q. Because you repair one compartment	14	itself doesn't fail, that's for sure. The need for
15	and you're causing a prolapse in another	15	the revision surgery is independent of the mesh, I
16	compartment; correct?	16	think that the context of that at the meeting was
17	A. Well, yeah, it goes for any kind of	17	not what was discussed here; and in these cases,
18	pelvic floor repair, mesh or not.	18	could be in some cases, the tissue is what fails.
19	MR. FREESE: Move to strike;	19	Q. In some cases.
20 21	nonresponsive.	20	A. Yeah. And in other cases, it wasn't
22	BY MR. FREESE:	21 22	put in right. But usually a revision is when the
23	Q. That was a known complication of a Prosima, was it not?	23	mesh comes out, it looks like when the mesh went in.
24	A. Yes.	24	It's a little dirtier, but it's intact. It doesn't have holes in it.
25	Q. Which used polypropylene mesh;	25	MR. FREESE: Move to strike as
	Page 423	23	Page 425
1	correct?	1	nonresponsive.
2	A. Yes.	2	BY MR. FREESE:
3	Q. And the question that Ms. Kluesner is	3	Q. You asked her to send you IFUs.
4	asking is about complications. So the need for	4	A. Yes.
5	revision surgeries independent of the mesh, that's	5	Q. To answer that question; correct?
6	not a true statement, is it, because but for the	6	A. Yes.
7	existence of the mesh, there wouldn't be a revision	7	Q. And she says this is for all IFUs,
8	surgery; correct, sir?	8	all TVTs, Gynemesh PS, and Artisyn Y's. Right?
9	MR. GAGE: Object to form.	9	A. Yes.
10	THE WITNESS: A revision surgery	10	Q. And you write would you like all of
11	might be necessary even if the mesh is functioning	11	these, and you said unfortunately yes.
12	as intended, but it might be a misplacement of the	12	A. Yes.
13	mesh or it might be a tearing free of the mesh, but	13	Q. Because you wanted to look at all of
14	the mesh when it's removed is appears the way it	14	them.
15	does when it goes in.	15	A. Yes.
16	MR. FREESE: Move to strike as	16	Q. And you did.
17	nonresponsive.	17	A. Yes.
18	BY MR. FREESE:	18	(Pause.)
19	Q. Dr. Weisberg, my question is simply	19	
			(Deposition Exhibit No. P-1668,
20	that you don't have revision surgery independent of	20	* *
20 21	that you don't have revision surgery independent of the mesh. The mesh is a necessary component of	21	5/8/14 E-Mail Chain, ETH.MESH.17636165
20 21 22	that you don't have revision surgery independent of the mesh. The mesh is a necessary component of needing a revision surgery, is it not?	21 22	5/8/14 E-Mail Chain, ETH.MESH.17636165 through ETH.MESH.17636167, was marked for
20 21 22 23	that you don't have revision surgery independent of the mesh. The mesh is a necessary component of needing a revision surgery, is it not? A. It may be.	21 22 23	5/8/14 E-Mail Chain, ETH.MESH.17636165
20 21 22	that you don't have revision surgery independent of the mesh. The mesh is a necessary component of needing a revision surgery, is it not?	21 22	5/8/14 E-Mail Chain, ETH.MESH.17636165 through ETH.MESH.17636167, was marked for

34 (Pages 422 to 425)

	Page 426		Page 428
1	Q. Dr. Weisberg, I'm going to show you	1	with these retrospective/prospective studies is,
2	what I've marked as P-1668. Have you seen that	2	they are often conducted in single centers and the
3	document before, sir?	3	authors do not always meticulously describe the
4	A. Let me read it, please.	4	methods for data collection and analysis. I also
5	Q. All right.	5	believe that the size of the cohorts would not allow
6	(Pause.)	6	for a meta-analysis. We would need several
7	THE WITNESS: Okay. Yes, I'm	7	larger-scale studies. I tried to select the
8	familiar with this.	8	information that was statistically significant,
9	BY MR. FREESE:	9	however the information wasn't always clear in the
10	Q. Did you review this in preparing your	10	documents and sometimes there was no P values.
11	for your deposition?	11	These only give us an indication that the number of
12	A. I reviewed a lot of documents. I	12	studies for TVT makes me think that the overall TVT
13	don't know if I reviewed this at that time, but I'm	13	is no less safer than traditional surgery. But,
14	familiar with the e-mail.	14	again, we would need robust, randomized,
15	Q. Who is Dr. Caroline Charles?	15	multicenter, large-scale trials to confirm every
16	A. She's a medical writer.	16	single point.
17	Q. Paid for by Ethicon?	17	Do you see that?
18	A. Yes.	18	A. I do.
19	MR. GAGE: Object to form.	19	Q. Is that a true statement?
20	BY MR. FREESE:	20	A. I believe it is.
21	Q. What does she write?	21	Q. Did you
22	A. She is the one that takes our	22	A. For a limited number of studies that
23	information that we gather for our clinical	23	she looked at. What I have to establish here is
24	evaluation reports that we do on all of our products	24	whether she was doing whether the clinical
25	on a regular basis and puts them into the format	25	evaluation report she did had a limited number of
	Page 427		Page 429
1	that's required.	1	Page 429 years of studies that she that she looked at. I
1 2		1 2	
	that's required. Q. Was she helping on the Health Canada response?		years of studies that she that she looked at. I
2	that's required. Q. Was she helping on the Health Canada response? A. I don't believe so.	2	years of studies that she that she looked at. I don't know that. I don't remember. Q. Can we agree that as of May 2014, there were no robust, randomized, multicenter,
2 3 4 5	that's required. Q. Was she helping on the Health Canada response? A. I don't believe so. Q. Why is she giving information to	2 3 4 5	years of studies that she that she looked at. I don't know that. I don't remember. Q. Can we agree that as of May 2014, there were no robust, randomized, multicenter, large-scale trials to confirm every single point
2 3 4 5 6	that's required. Q. Was she helping on the Health Canada response? A. I don't believe so. Q. Why is she giving information to Stacy Kluesner, re: Health Canada request?	2 3 4 5 6	years of studies that she that she looked at. I don't know that. I don't remember. Q. Can we agree that as of May 2014, there were no robust, randomized, multicenter, large-scale trials to confirm every single point that is being discussed here?
2 3 4 5	that's required. Q. Was she helping on the Health Canada response? A. I don't believe so. Q. Why is she giving information to Stacy Kluesner, re: Health Canada request? A. Stacy may have reached out to and	2 3 4 5 6 7	years of studies that she that she looked at. I don't know that. I don't remember. Q. Can we agree that as of May 2014, there were no robust, randomized, multicenter, large-scale trials to confirm every single point that is being discussed here? A. No, that's not
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	that's required. Q. Was she helping on the Health Canada response? A. I don't believe so. Q. Why is she giving information to Stacy Kluesner, re: Health Canada request? A. Stacy may have reached out to and this is a guess, but I think I recall that Stacy may have reached out to her to get some information to include in the Health Canada request. Q. Do you see the question she poses: Can you please assist in the rationale for why no statistical methods were used to analyze the data, different methodologies, endpoints, statistical plans, et cetera? This can be generic. Do you see that? A. I'm trying to see where you're reading. What Q. The the first A. Which date? Q. The full paragraph here on the front page here (Indicating).	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	years of studies that she that she looked at. I don't know that. I don't remember. Q. Can we agree that as of May 2014, there were no robust, randomized, multicenter, large-scale trials to confirm every single point that is being discussed here? A. No, that's not MR. GAGE: Object to form. THE WITNESS: That's not true. BY MR. FREESE: Q. That is what she says, is it not? MR. GAGE: Object to form. THE WITNESS: Well, that may be what she says, but that's not true. What she says is that you can't take these studies and put them together to create a meta-analysis because the ways that they were done weren't exactly or weren't similar enough to be able to merge them into one new study. That's what a meta-analysis is. MR. FREESE: I understand that. And you agree with that, that there was not enough studies in existence as of 2014 to even do a proper

35 (Pages 426 to 429)

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Page 430
                                                                                                            Page 432
 1
     BY MR. FREESE:
                                                             1
                                                                      Q.
                                                                            The paid-for Ethicon consultant;
 2
                                                             2
                                                                  correct?
               That is what Dr. Charles is saying,
         Q.
                                                             3
 3
     is it not?
                                                                           MR. GAGE: Object to form.
 4
                                                             4
              MR. GAGE: Object to form.
                                                                  BY MR. FREESE:
 5
              THE WITNESS: Let me just read this
                                                             5
                                                                            Right?
                                                                      Q.
                                                             6
 6
     again: Very wide variety of methods, patient
                                                                      A.
                                                                            He has consulted with Ethicon.
 7
     selection, variable statistical analysis of POP-Q
                                                             7
                                                                      Q.
                                                                            And so my question to you, sir, is
8
                                                             8
                                                                  since the time -- apparently Dr. Charles is just --
     endpoint, et cetera. These
9
     retrospective/prospective studies is that they are
                                                             9
                                                                  she's unaware of all these studies you're talking
10
     often conducted in single centers.
                                                             10
                                                                  about.
                                                            11
11
              Okay. So she's talking about a lot
                                                                           MR. GAGE: Object to form.
     of the publications that were not randomized,
                                                            12
                                                                           THE WITNESS: Well, she doesn't say
12
13
     controlled. The size of the cohorts would not allow
                                                            13
                                                                  whether she's aware of them or not.
14
     for a meta-analysis, need several larger-scale
                                                            14
                                                                  BY MR. FREESE:
15
     studies. I tried to select information that was
                                                            15
                                                                            Well, she says they don't exist and
                                                                      O.
16
     statistically significant. Information wasn't
                                                            16
                                                                  that she can conclude no more -- that TVT is no less
17
     always clear and there were no P values. This gives
                                                            17
                                                                  safer than traditional surgery. Do you see that
18
     us an indication of the number of studies for TVT
                                                            18
                                                                  line?
19
     and makes us think that overall TVT is no less safe
                                                            19
                                                                           MR. GAGE: Object to form.
                                                            20
20
     than traditional surgery, but again we would need
                                                                           THE WITNESS: I see that line.
21
     robust, randomized, multicenter, large-scale trials
                                                            21
                                                                  BY MR. FREESE:
22
     to confirm every patient.
                                                            22
                                                                            And my question to you, sir, is, is
                                                            23
                                                                  that a different way of saying it's no more
23
     BY MR. FREESE:
24
               Do you agree with that?
                                                            24
                                                                  dangerous than traditional surgery?
         Q.
25
         A.
               I really don't.
                                                            25
                                                                            Well, you'd have to ask her what she
                                                                                                            Page 433
                                               Page 431
1
         Q.
               Did anybody tell Dr. Charles she was
                                                             1
                                                                  meant by that.
 2
                                                             2
     wrong?
                                                                      Q.
                                                                            I'm asking you --
 3
                                                             3
               I did not. I don't specifically
                                                                      A.
                                                                            No.
                                                             4
 4
     remember discussing this, although I suspect -- I'm
                                                                            -- as a medical director, what does
                                                                      O.
                                                             5
 5
     remembering that we did discuss it and whether I
                                                                  it mean to be no less safer than?
     gave an answer or not -- I know I didn't give it to
                                                             6
                                                                            Well, in the statistical world, there
 7
     her. Whether somebody else answered her or not, I
                                                             7
                                                                  are equivalence studies which says things like no
8
                                                             8
     don't know.
                                                                  less safe or no less effective.
9
                                                             9
         Q.
               Well, sitting here today, you don't
                                                                           And then there are other studies
10
     have your response in front of you; correct?
                                                            10
                                                                  which are powered and controlled for, being able to
               No, I don't.
                                                            11
                                                                  say it's better, and there are many, many, many
11
         A.
12
               You don't remember what your response
                                                            12
                                                                  studies that show that.
         Q.
                                                            13
13
                                                                           The -- of those hundred randomized,
     was; correct?
14
                                                            14
                                                                  controlled studies, the safety and effectiveness has
         A.
               It would have been the same as it was
15
                                                            15
                                                                  been consistent, not to the exact percentage, but
     just now.
16
                                                            16
                                                                  within a highly successful range, and the safety has
               As we sit here today, did Ethicon
         Q.
     ever do any more robust, randomized, multicenter,
                                                            17
                                                                  been also -- they have -- this is a device that has
17
                                                            18
     large-scale trials after 2014 to confirm any of the
                                                                  shown to be safe.
18
                                                            19
19
     questions that Ms. Kluesner had at that time?
                                                                           MR. FREESE: Move to strike as
20
                                                            20
               We have over the -- the life of TVT
                                                                  nonresponsive.
21
     probably a hundred randomized, controlled trials,
                                                            21
                                                                           I didn't ask you anything at all
                                                            22
                                                                  about TVT, sir. I simply asked you to define what
22
     including thousands of patients, and some of them go
     out as long as 17 years.
                                                             23
                                                                  no less safer means. That's all I asked you.
23
24
         Q.
               Yeah, Dr. Nilsson's study.
                                                            24
                                                                           Do you understand that was my
25
                                                            25
               Dr. Nilsson's study.
                                                                  question?
         A.
```

36 (Pages 430 to 433)

	Page 434		Page 436
1	THE WITNESS: That's in the beginning	1	looking at page 5, what was requested in part was
2	of my question the beginning of my answer.	2	the labeling that contains up-to-date information on
3	BY MR. FREESE:	3	potential complications as listed by Health Canada.
4	Q. Well, I move to all I asked you	4	A. Yes.
5	was, what does no less safer mean.	5	Q. And if you'll look on page 9, it says
6	A. It's a statistical term.	6	results of investigation. Do you see that?
7	MR. FREESE: I move to strike	7	A. Yes.
8	everything after it's everything other than "It's	8	Q. And it says: Changes are required in
9	a statistical term."	9	the global labeling due to Health Canada's Section
10	(Pause.)	10	39 request and to align with FDA's proposed rule.
11	MR. FREESE: Dr. Weisberg, I want to	11	Do you see that?
12	show you what I've marked as P-1669.	12	A. Yes.
13		13	Q. And I think you mentioned this
14	(Deposition Exhibit No. P-1669,	14	earlier, but this started off as just changing the
15	6/2/14 PRE14-055S Health Canada Section 39	15	IFUs for Health Canada. At some point, the company
16	Request and Response, ETH.MESH.17639467,	16	decided to change its IFUs worldwide.
17	was marked for identification.)	17	A. Yes.
18		18	Q. For all of the TVTs, the Gynemesh,
19	BY MR. FREESE:	19	and Artisyn Y?
20 21	Q. And this is a it looks like a	20 21	A. Yes.
22	Power Point presentation on the Health Canada	22	Q. And was this document created in the
23	Section 39 request and response. Do you see that? A. Yes.	23	normal course of business by Ethicon? A. Yes.
24	Q. Dated June 2nd, 2014?	24	Q. By Ethicon employees?
25	A. Yes.	25	A. Yes.
	Page 435		Page 437
1	Q. Are you familiar with this document?	1	Q. At or about the time that it was
2	A. I am.	2	prepared on June 2nd, 2014?
3	Q. Did you help author any part of it?	3	A. Yes.
4	A. I didn't put it together, but it was	4	Q. And does the information here to the
5	put together with the team that I worked with.	5	best of your knowledge appear to be correct and
6	Q. All right. Can you describe for me	6	accurate?
7	what this document is, please, sir?	7	A. Yes.
8	A. Let me just look through it to make	8	Q. And if you'll look on page
9	sure that	9	starting on page 12. It says labeling changes to be
10	(Pause.)	10	made. Do you see that?
11	THE WITNESS: This is a I believe	11	A. Yes.
12	this is a quality board document.	12	Q. And it lists across there the changes
13	BY MR. FREESE:	13	made to the labeling for TVT, Gynemesh PS, and
14	Q. For Health Canada?	14	Artisyn. Do you see that?
15	A. Yes. I'm not a hundred percent sure.	15	A. Yes.
16	This is obviously a presentation made to people not	16	Q. And if you'll they have an adverse
17	directly involved on the Health Canada team, so this	17	events section. Do you see that?
18	is a presentation that was made, it looks like a	18	A. I do.
19	presentation that was for it was for quality	19	Q. Then there's a labeling modification,
20	board review, yeah. I'm sorry.	20	do you see that, for the adverse events?
21	Q. And it describes what went on, that	21	A. Yes.
22	is, the request coming into Johnson & Johnson from	22	Q. And then there's a section, labeling
23	Health Canada March 24th, 2014?	23	additions, adverse events section. Do you see that?
24 25	A. Yes.Q. And it says requested, and I'm	24 25	A. Yes. Q. And that means that that the
رک	Q. And it says requested, and I in		Q. And that means that that the

37 (Pages 434 to 437)

	Page 438		Page 440
1	things listed on here were additions to the IFU that	1	there, orange is attributing the adverse event to
2	did not previously exist; correct?	2	litigation; correct?
3	MS. KABBASH: Rich, are you talking	3	A. Yes.
4	about page 15 of the slide deck?	4	Q. Blue is attributed to nonlitigation;
5	MR. FREESE: Yes.	5	correct?
6	THE WITNESS: 15?	6	A. Correct.
7	MR. FREESE: Yes, sir.	7	Q. And the green line is the rate?
8	THE WITNESS: I'm sorry.	8	A. Yes.
9	MR. FREESE: I'm walking you through	9	Q. Okay.
10	each page.	10	My question, sir, is, how does
11	THE WITNESS: Okay.	11	Ethicon track whether or not a complaint is
12	MR. FREESE: Page 12 lists the	12	litigation related or not?
13	adverse events, under new section other adverse	13	A. Well, they can't be a hundred percent
14	events.	14	accurate, but the complaints that have come from
15	THE WITNESS: Yes.	15	doctors or patients themselves are what you see at
16	MR. FREESE: Page 13 is labeling	16	the top of each column in blue.
17	modification adverse events, same for page 14. And	17	Everything in orange comes from
18	page 15 is labeling additions adverse events	18	attorneys.
19	section.	19	Q. So if a lawsuit was filed is this
20	Do you see that?	20	like a lawyer files an adverse event or is Ethicon
21	THE WITNESS: Right.	21	simply counting the number of lawsuits filed against
22	MR. FREESE: Okay.	22	it in order to come up with that number?
23	THE WITNESS: Page 14 is labeling	23	A. Any time we learn of an adverse
24	modifications. Page 15 is labeling additions.	24	event, whether it's walking down the street and
25	BY MR. FREESE:	25	talking to somebody, reading an article in the
	Page 439		Page 441
1	Q. And it lists here all the additions	1	paper, casually being at dinner with somebody who
2	to the IFU in the adverse events section; correct?	2	said, you know, I had your device and it didn't
3	A. Correct.	3	work, even to the point of I don't like the color of
4	Q. It lists that there all these	1 1	the how all of that according as a complaint. And
		4	the box, all of that goes in as a complaint. And
5	things are going to be put into TVT's IFUs; correct?	5	it's the role of every Ethicon employee to report
5 6	things are going to be put into TVT's IFUs; correct? A. That's correct.	5 6	it's the role of every Ethicon employee to report any adverse event that they learn about.
5 6 7	things are going to be put into TVT's IFUs; correct? A. That's correct. Q. And one of the strike that.	5 6 7	it's the role of every Ethicon employee to report any adverse event that they learn about. Q. I understand, but my question is, I
5 6 7 8	things are going to be put into TVT's IFUs; correct? A. That's correct. Q. And one of the strike that. And then if you'll look over at page	5 6 7 8	it's the role of every Ethicon employee to report any adverse event that they learn about. Q. I understand, but my question is, I mean, you're tracking literally numbers of
5 6 7 8 9	things are going to be put into TVT's IFUs; correct? A. That's correct. Q. And one of the strike that. And then if you'll look over at page 18, Dr. Weisberg, there's a there's some	5 6 7 8 9	it's the role of every Ethicon employee to report any adverse event that they learn about. Q. I understand, but my question is, I mean, you're tracking literally numbers of complaints and ascribing them to litigation in here.
5 6 7 8 9	things are going to be put into TVT's IFUs; correct? A. That's correct. Q. And one of the strike that. And then if you'll look over at page 18, Dr. Weisberg, there's a there's some several graphs. Do you see that?	5 6 7 8 9	it's the role of every Ethicon employee to report any adverse event that they learn about. Q. I understand, but my question is, I mean, you're tracking literally numbers of complaints and ascribing them to litigation in here. A. Well, the information is given to us
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5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	things are going to be put into TVT's IFUs; correct? A. That's correct. Q. And one of the strike that. And then if you'll look over at page 18, Dr. Weisberg, there's a there's some several graphs. Do you see that? A. I do. Q. And are these charts intended to document adverse event reports? A. Yes. Q. And there's a spike in adverse event reports between, I guess, March-April of 2013 through December of 2013; is that correct? A. That's correct. Q. What was the purpose of these charts being prepared? A. We do this every week with all of our complaints during our adverse event meeting. We do it weekly and we do it monthly so we can track	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	it's the role of every Ethicon employee to report any adverse event that they learn about. Q. I understand, but my question is, I mean, you're tracking literally numbers of complaints and ascribing them to litigation in here. A. Well, the information is given to us by our legal department that these many that the they received notices on these cases and they're counted as complaints. Q. That's my point. So if a if a woman has a complication from a TVT mesh, has surgery, multiple surgeries, and doesn't file a lawsuit, that doesn't show up in this list unless she or her doctor reports it; correct? A. That's correct. Q. If however but if a lawsuit's filed on behalf of that woman where she's got a complication, it gets counted; correct? A. That's correct.
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Page 444 Page 442 1 report it, it never would have gotten counted, would to see what we can learn from it and to see whether 2 2 there's something we can do to make sure that we it? 3 3 A. That's correct. minimize the bad things that happen when people have 4 4 O. So the lawsuits do help you track operations. 5 more accurately the number of adverse events, do 5 Well, what has Ethicon done to Q. 6 6 minimize the bad things that happen from they not? 7 7 complications because of these litigation charts MR. GAGE: Object to form. 8 8 THE WITNESS: Well, it gives us the that you got here? opportunity to look into all these cases. 9 9 A. Well, you know, you're asking a very 10 BY MR. FREESE: 10 broad question. 11 11 Because otherwise you might have an Q. Yes, sir. adverse event that didn't otherwise get reported; 12 The things that have happened -- I 12 A. 13 13 correct? can give you some general -- I'll have to give you a 14 14 broad answer. That's correct. A. 15 MR. GAGE: Object to form. 15 Well, let me withdraw the question Q. 16 BY MR. FREESE: 16 then. 17 17 You would agree with me that the A. Okay. 18 number of adverse events are normally well 18 Do you agree with me, Dr. Weisberg, underreported, are they not? 19 19 that to the extent that the lawsuits have alerted I believe that's true. 20 20 A. Ethicon to complications arising out of the use of 21 O. In other words, the number of 21 its products that it didn't otherwise know of is a 22 complications from TVT, generally, the ones that are 22 good thing? 23 23 actually reported are much less than the actual MR. GAGE: Object to form. 24 THE WITNESS: I don't know that we 24 complications that are existing in society as a 25 got any new complications or adverse events, but 25 whole. Page 443 Page 445 1 A. I think that's generally true. 1 certainly we're able to see the -- how widespread, 2 2 at least complaints of such events are, and, yes, it Q. All right. 3 And you're not ascribing any question 3 helps us. as to the merits or lack of merits if it's 4 BY MR. FREESE: 4 5 Because that -- these lawsuits that 5 litigation -- strike that. 6 In the columns that are listing the 6 are being reported here may very well alert you to 7 number of complaints versus -- litigation versus 7 complications you wouldn't otherwise have seen in 8 8 nonlitigation, this is not an attempt to quantify by any reporting database; correct? 9 9 merits whether or not it's a valid complaint; MR. GAGE: Object to form. 10 correct? 10 THE WITNESS: That's correct. Any 11 11 time we learn about a complication and can A. Not at all. 12 What is the purpose of tracking it by 12 investigate it and see what the story is, it makes Q. litigation as opposed to nonlitigation? 13 13 us better. 14 Well, I can't really answer why they 14 BY MR. FREESE: 15 do that, except to explain why there's a spike, and 15 And who at Ethicon's in charge of O. 16 that spike may mean that more of these cases are 16 investigating all of these lawsuits to see whether being reported that weren't being reported at all. 17 or not they are valid adverse events? 17 18 18 And it's still a spike. You know, we still need to MR. GAGE: Object to form. THE WITNESS: Our quality department 19 19 look into it. 20 20 tries to investigate every case. Sometimes with the Sometimes the --21 Q. Go ahead. 21 litigation cases, we don't get answers. 22 22 BY MR. FREESE: Sometimes the litigation reports are A. harder to get information from to try to investigate 23 23 Q. When -- strike that. 24 the complaints, but every one of them -- there's an 24 You understand that many, many, many attempt to investigate every complaint that comes in 25 of the women who have filed lawsuits against J & J 25

39 (Pages 442 to 445)

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Page 446
                                                                                                        Page 448
1
     over their TVT products or their -- or their
                                                           1
                                                               BY MR. FREESE:
2
                                                           2
     prolapse products have had to have revision
                                                                         Who in quality tracks whether or not
3
                                                           3
     surgeries; correct? You do know that.
                                                               surgeries are necessary in the view of Ethicon?
4
             MR. GAGE: Object to form.
                                                           4
                                                                        MR. GAGE: Beyond the scope.
5
              THE WITNESS: I know that some have.
                                                           5
                                                               Objection; beyond the scope.
6
     I don't know how you're defining many, many, many.
                                                           6
                                                                        THE WITNESS: Each individual case is
7
              MR. FREESE: A -- a -- not a hundred
                                                           7
                                                               evaluated, and I don't know that we keep a record of
8
                                                           8
     percent, but a double digit percent of the women who
                                                               how many need un -- had a what we consider
9
     filed complaints have had to have additional
                                                           9
                                                               unnecessary surgery or may not have needed surgery.
10
     surgeries arising from complications out of the use
                                                          10
                                                                        I mean, you know, we're very limited.
11
     of a POP or SUI product.
                                                          11
                                                               We don't know the patient. We haven't seen the
12
              MR. GAGE: Object to form.
                                                               patient. We haven't seen the X-rays, et cetera, but
                                                          12
13
     BY MR. FREESE:
                                                          13
                                                               we do track that and if you look at any individual
14
                                                          14
                                                               case, if we were able to gather enough information,
               You know that.
         O.
15
               I can't answer that specifically. I
                                                          15
                                                               we may make a comment that there were other ways
         A.
16
     would have to look at it case by case. There are
                                                          16
                                                               that may have been taken care of this complaint.
    lots of reasons that people need additional surgery.
                                                          17
                                                               BY MR. FREESE:
17
18
               Well, let me ask you this, sir: Is
                                                          18
                                                                         All right. But my question to you
19
     it your belief that any of the surgeries that are
                                                          19
                                                               is, who is in charge of that department -- that
                                                          20
     being done by doctors in this country for
20
                                                                quality assurance department in Ethicon that tracks
21
     complications arising out of the use of an SUI or
                                                          21
                                                                whether or not surgeries are necessary?
22
     POP product are unnecessary surgeries?
                                                          22
                                                                        MR. GAGE: Objection; scope.
              MR. GAGE: Object to form; beyond the
                                                          23
                                                                        THE WITNESS: That's a compound
23
24
                                                          24
                                                               question. Who's in charge of --
    scope.
                                                          25
                                                                        MR. FREESE: Of -- you said the
25
             THE WITNESS: I can't answer that.
                                              Page 447
                                                                                                        Page 449
1
     BY MR. FREESE:
                                                           1
                                                               person who tracks whether or not surgeries that
2
              As you sit here today, you have no
                                                           2
                                                               women are having to correct complications from mesh
3
    evidence that any surgery being performed on a woman
                                                           3
                                                               is done in the quality department. I'm asking you
    to repair a complication from an injury related to
                                                           4
                                                               who's in charge of that.
4
5
                                                           5
    mesh was an unnecessary surgery.
                                                                   A.
                                                                        I don't know --
6
             MR. GAGE: Object to form; beyond the
                                                           6
                                                                        MR. GAGE: Objection; scope.
7
                                                           7
                                                                        THE WITNESS: I'm sorry. I don't
    scope.
8
                                                           8
             THE WITNESS: I can't answer that.
                                                               know that it's tracked. It's investigated, but I
9
                                                           9
    BY MR. FREESE:
                                                               don't know that it's tracked.
10
         Q. Has anybody at Ethicon ever looked at
                                                          10
                                                                        MR. FREESE: I may have misunderstood
     that question, whether or not women are having
                                                          11
                                                               your testimony.
11
12
    unnecessary surgeries?
                                                          12
                                                                        (Pause.)
13
             MR. GAGE: Object to form; beyond the
                                                          13
                                                               BY MR. FREESE:
14
                                                          14
                                                                   Q. Did Health Canada ask any questions
    scope.
15
             THE WITNESS: We try to look at every
                                                          15
                                                               about degradation of the mesh?
16
    complaint individually and there are some that
                                                          16
                                                                   A.
                                                                         No.
    appear to have surgery that could have been avoided.
                                                          17
                                                                         And did you supply them any
17
                                                                    Q.
                                                               information about evidence of degradation of the
18
             MR. FREESE: Okay.
                                                          18
19
             THE WITNESS: And others where it
                                                          19
                                                               mesh?
20
    appears that it was a necessary surgery.
                                                          20
                                                                         The mesh is clinically nondegradable,
21
    BY MR. FREESE:
                                                          21
                                                               and that's in the IFU.
22
                                                          22
         Q.
              Who tracks that?
                                                                        MR. FREESE: Move to strike,
23
             MR. GAGE: Object to form --
                                                          23
                                                               nonresponsive.
24
             THE WITNESS: Quality.
                                                          24
                                                               BY MR. FREESE:
25
             MR. GAGE: -- beyond the scope.
                                                          25
                                                                   Q. I simply asked you, did you supply
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40 (Pages 446 to 449)

	Page 450		Page 452
1	any information to Health Canada regarding	1	MR. FREESE: TVTs were causing
2	degradation of the mesh?	2	complication in women. Are you familiar with that
3	A. Yes.	3	report?
4	Q. And was it supplied because it was	4	MR. GAGE: Object to form.
5	already in the IFU?	5	THE WITNESS: Yes, I am.
6	A. Yes.	6	BY MR. FREESE:
7	Q. So we can look at that. Is that	7	Q. Was the PA Consulting study shared
8	the phrase, under the action section, of animal	8	with Health Canada?
9	studies show that implantation of Prolene mesh	9	A. No.
10	elicits a minimal inflammatory reaction in tissues	10	MR. FREESE: I'm trying to zip
11	which is transient followed by the deposition of	11	through my questions here to get us going.
12	thin fibrous tissue layers that can grow through the	12	Let's go ahead I think he needs to
13	interstices of the mesh, thus incorporating the mesh	13	change the tape anyway. Let's take five minutes.
14	into adjacent tissue. The material is not absorbed,	14	Let me look at my notes.
15	nor is it subject to degradation or weakening or	15	THE VIDEO TECHNICIAN: The time is
16	action of tissue enzymes, is that the phrase you	16	1:06. We are going off the record.
17	were referring to?	17	
18	A. That's correct.	18	(A discussion off the record
19	Q. And that didn't change.	19	occurred.)
20	A. That didn't change.	20	
21	Q. And they didn't ask you about that.	21	(A luncheon recess was taken from
22	A. No, they didn't.	22	1:07 p.m. until 1:56 p.m.)
23	Q. Did you share with them any of your	23	^
24	studies showing that mesh did degrade?	24	(Whereupon, the following discussion
25	MR. GAGE: Object to form.	25	took place off the videotape record:
	Page 451		Page 453
1	THE WITNESS: We discussed a study	1	
2	that was done a long time ago and concluded that any	2	MR. GAGE: So, Madam Court Reporter,
3	degradation, as minimal as it is, did not affect the	3	I have on my speakerphone, my being William Gage,
4	strength or the weight of it was a suture study	4	Rich Bernardo, who is counsel for Ethicon and
5	and it was in dogs. It did not affect either the	5	Johnson & Johnson, in this litigation along with
6	strength or the weight of the polypropylene.	6	Alex Barlow and Rich Freese.
7	So, clinically, it doesn't it	7	And Mr. Freese has asked us to make
8	doesn't degrade in any way to it's not clinically	8	certain stipulations with regard to some of the
9	significant. It's not clinically important.	9	documents that were shown to Dr. Weisberg over the
10	MR. FREESE: Move to strike as	10	past two days, and I believe we have an
11	nonresponsive.	11	understanding or an agreement that we need to
12	BY MR. FREESE:	12	memorialize on the record.
13	Q. Dr. Weisberg, did you share the PA	13	MR. BERNARDO: This is Rich Bernardo,
14	Consulting study with Health Canada?	14	who, for the record, is not at the deposition, but
15	A. The PA Consulting	15	is calling in telephonically.
16	MR. GAGE: Object to form.	16	Mr. Freese and myself and some
17	BY MR. FREESE:	17	colleagues representing Ethicon have been engaged in
18	Q. First of all, are you familiar with	18	ongoing discussions with respect to evidentiary
19	the PA Consulting study?	19	issues and documentary issues; and we've come to an
20	MR. GAGE: Object to form.	20	agreement for purposes of certain cases, including
21	THE WITNESS: I would need to see it.	21	the Texas cases in this litigation, not to object on
22	MR. FREESE: It's a London-based	22	the grounds of business record to e-mails composed
23	company that Ethicon hired to review all the science	23	or created by Ethicon employees.
24	and literature on why	24	But we do point out, as we have in
25	THE WITNESS: Oh	25	our prior discussions with Mr. Freese, that we do

41 (Pages 450 to 453)

Page 456 Page 454 1 not agree as a legal matter that every e-mail the 1 things that we pointed out we would not agree to as 2 2 company creates does constitute a business record. falling within business records, even though they 3 3 are e-mails, are e-mails of a personal nature or Rather, we're doing this as an accommodation to get 4 by a number of issues and we certainly do reserve 4 e-mails of such language that clearly are not 5 5 our right in certain circumstances to raise that business related and other examples like that. 6 6 We've had those discussions a number issue. 7 7 of times. I think we've come to agreement on that, And we will also agree as to those 8 8 documents or e-mails that are not created by and that's one of the reasons that I'm reserving for 9 Ethicon, but indicate from their face that they were 9 Ethicon its right to object to certain documents and 10 received by an Ethicon employee, that they were, in 10 not making a blanket statement here. 11 11 fact, received by that Ethicon employee in MR. FREESE: Yeah, and that's fine, connection with his business and received by any Rich, and I don't think we have any of those in 12 12 13 individual from whose custodial file the record was 13 front of us today, so --14 collected. 14 MR. BERNARDO: Perfect. 15 Rich, does that accurately reflect 15 MR. GAGE: Are you all done? MR. BARLOW: Yeah. 16 what you and I have been discussing? 16 17 MR. FREESE: Yeah, with a couple of 17 MR. GAGE: Thank you, Rich. We very additions: That the recipient of the e-mail or the 18 18 much appreciate it. 19 holder of the e-mail in their custodial file was on 19 MR. BERNARDO: My pleasure.) 20 20 notice of the information contained therein. 21 And the only other thing I would say 21 (A discussion off the record 22 is, you said you -- I understand you're not making a 22 occurred.) blanket agreement that all e-mails forever are 23 23 business records of Johnson & Johnson and you are 24 THE VIDEO TECHNICIAN: The time is 24 25 25 reserving that right. 2:01. We're back on the record. Page 455 Page 457 1 In cases other than the ones that 1 2 you're agreeing -- you're not going to reserve it in 2 **EXAMINATION** 3 this one because we haven't accomplished anything 3 4 4 then. You're reserving it generally, but you're not BY MR. GAGE: 5 5 Good afternoon, Dr. Weisberg. My going to assert it in this litigation on the 6 particular documents that we're making the agreement 6 name is William Gage. I'm an attorney for Ethicon 7 7 and Johnson & Johnson, and I have some questions to on. 8 8 MR. BERNARDO: That is correct. ask vou. 9 9 MR. BARLOW: And by this litigation, A. Okay. 10 you mean the MDL litigation, the New Jersey 10 Q. The first document that you have litigation, or Mr. Freese's cases. Right? 11 there in front of you is marked P-1608; correct? 11 12 MR. BERNARDO: That is correct. 12 A. 13 13 MR. GAGE: And so now I think the O. And you were asked some questions, I 14 only task that remains at hand is, we do have to go 14 think yesterday, about that document; correct? 15 through and pull out of the stack of the exhibits 15 A. Yes. 16 those documents which do not fall within the scope 16 Q. Would you tell the jury what this 17 of this agreement, things such as the list of 17 document is? 18 18 witnesses that he -- I mean, the list of people on The document's a request from Health Canada for additional information on some of our 19 19 the various teams that he created and a couple of 20 20 medical devices. other documents. 21 MR. BARLOW: Documents that weren't 21 And you've been testifying for a day 22 22 created by Ethicon -and a half about generally the Health Canada 23 request; correct? 23 MR. BERNARDO: One additional point 24 that Mr. Gage reminds me of is, Mr. Freese, in 24 Α. Correct. connection with our discussions, one example of 25 25 And this is the document that Q.

42 (Pages 454 to 457)

	Page 458		Page 460
1	constitutes the Health Canada request that was sent	1	Q. Is it a response with attachments?
2	to Ethicon and about which we have generally been	2	A. It's a response letter with a number
3	discussing for the past day and a half; correct?	3	of attachments.
4	A. Yes.	4	Q. Was that document and the
5	MR. GAGE: All right. Dr. Weisberg,	5	attachments, were they made at or near the time of
6	I'm handing you what number is the exhibit number	6	the events described in the documents by person or
7	on that? What is the next exhibit number, ma'am; do	7	persons with actual knowledge?
8	you know?	8	A. Yes.
9	MR. FREESE: It's going to be on	9	Q. And was the writing and those
10	whatever those stickers are.	10	attachments made in the regular course of Ethicon's
11	(Pause.)	11	business?
12	MR. GAGE: Does it still say P? It	12	A. Yes.
13	doesn't say P-1670.	13	Q. And was it Ethicon's regular business
14	MR. FREESE: I think they have been	14	practice to make that record or document?
15	saying that. I was kind of thrown off by that.	15	A. Yes.
16	MR. GAGE: It says P, even if it's	16	Q. And Dr. Weisberg, as I understand it,
17	one of my exhibits, a defense exhibit?	17	you were the medical director the Ethicon medical
18	THE COURT REPORTER: (Indicating.)	18	director who was the most heavily involved in the
19	THE VIDEO TECHNICIAN: Off the	19	Health Canada response; is that correct?
20	record?	20	A. That's correct.
21	MR. FREESE: Off the record. Sure.	21	Q. Tell the jury, if you would, a little
22	THE VIDEO TECHNICIAN: The time is	22	bit about your background and training, just
23	2:03. We're going off the record.	23	briefly.
24		24	A. I am a gynecologist. I practiced for
25	(A discussion off the record	25	from I was at Thomas Jefferson University
	Page 459		Page 461
1	occurred.)	1	Hospital from 1972 through the year 2000, practicing
2		_	
		2	gynecology. After that, I came to work at Ethicon
3	THE VIDEO TECHNICIAN: The time is	3	gynecology. After that, I came to work at Ethicon as a medical director.
3 4	THE VIDEO TECHNICIAN: The time is 2:04. We're back on the record.		
	2:04. We're back on the record.	3 4 5	as a medical director. Q. So what did you do between what do you do now?
4 5 6	2:04. We're back on the record. (Deposition Exhibit No. D-1, Ethicon	3 4 5 6	as a medical director. Q. So what did you do between what do you do now? A. I retired on August the 31st and
4 5 6 7	2:04. We're back on the record. (Deposition Exhibit No. D-1, Ethicon Response to Section 39 Request and	3 4 5 6 7	as a medical director. Q. So what did you do between what do you do now? A. I retired on August the 31st and started back as a contractor part-time for Ethicon
4 5 6 7 8	2:04. We're back on the record. (Deposition Exhibit No. D-1, Ethicon Response to Section 39 Request and Attachments, ETH.MESH.22631022 through	3 4 5 6 7 8	as a medical director. Q. So what did you do between what do you do now? A. I retired on August the 31st and started back as a contractor part-time for Ethicon on September 1st, and that's what I'm doing now.
4 5 6 7 8 9	2:04. We're back on the record. (Deposition Exhibit No. D-1, Ethicon Response to Section 39 Request and Attachments, ETH.MESH.22631022 through ETH.MESH.22632029, was marked for	3 4 5 6 7 8 9	as a medical director. Q. So what did you do between what do you do now? A. I retired on August the 31st and started back as a contractor part-time for Ethicon on September 1st, and that's what I'm doing now. Q. So were you a medical director at
4 5 6 7 8 9	2:04. We're back on the record. (Deposition Exhibit No. D-1, Ethicon Response to Section 39 Request and Attachments, ETH.MESH.22631022 through	3 4 5 6 7 8 9	as a medical director. Q. So what did you do between what do you do now? A. I retired on August the 31st and started back as a contractor part-time for Ethicon on September 1st, and that's what I'm doing now. Q. So were you a medical director at Ethicon from 2000 through the mid part of 2015?
4 5 6 7 8 9 10 11	2:04. We're back on the record. (Deposition Exhibit No. D-1, Ethicon Response to Section 39 Request and Attachments, ETH.MESH.22631022 through ETH.MESH.22632029, was marked for identification.)	3 4 5 6 7 8 9 10	as a medical director. Q. So what did you do between what do you do now? A. I retired on August the 31st and started back as a contractor part-time for Ethicon on September 1st, and that's what I'm doing now. Q. So were you a medical director at Ethicon from 2000 through the mid part of 2015? A. Yes.
4 5 6 7 8 9 10 11	2:04. We're back on the record. (Deposition Exhibit No. D-1, Ethicon Response to Section 39 Request and Attachments, ETH.MESH.22631022 through ETH.MESH.22632029, was marked for identification.) BY MR. GAGE:	3 4 5 6 7 8 9 10 11 12	as a medical director. Q. So what did you do between what do you do now? A. I retired on August the 31st and started back as a contractor part-time for Ethicon on September 1st, and that's what I'm doing now. Q. So were you a medical director at Ethicon from 2000 through the mid part of 2015? A. Yes. Q. And what, if any, gynecological
4 5 6 7 8 9 10 11 12 13	2:04. We're back on the record. (Deposition Exhibit No. D-1, Ethicon Response to Section 39 Request and Attachments, ETH.MESH.22631022 through ETH.MESH.22632029, was marked for identification.) BY MR. GAGE: Q. Dr. Weisberg, I'm handing you a	3 4 5 6 7 8 9 10 11 12 13	as a medical director. Q. So what did you do between what do you do now? A. I retired on August the 31st and started back as a contractor part-time for Ethicon on September 1st, and that's what I'm doing now. Q. So were you a medical director at Ethicon from 2000 through the mid part of 2015? A. Yes. Q. And what, if any, gynecological meshes were you responsible for during that
4 5 6 7 8 9 10 11 12 13 14	2:04. We're back on the record. (Deposition Exhibit No. D-1, Ethicon Response to Section 39 Request and Attachments, ETH.MESH.22631022 through ETH.MESH.22632029, was marked for identification.) BY MR. GAGE: Q. Dr. Weisberg, I'm handing you a document that is marked D-1. Are you familiar with	3 4 5 6 7 8 9 10 11 12 13 14	as a medical director. Q. So what did you do between what do you do now? A. I retired on August the 31st and started back as a contractor part-time for Ethicon on September 1st, and that's what I'm doing now. Q. So were you a medical director at Ethicon from 2000 through the mid part of 2015? A. Yes. Q. And what, if any, gynecological meshes were you responsible for during that timeframe?
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4 5 6 7 8 9 10 11 12 13 14 15 16	2:04. We're back on the record. (Deposition Exhibit No. D-1, Ethicon Response to Section 39 Request and Attachments, ETH.MESH.22631022 through ETH.MESH.22632029, was marked for identification.) BY MR. GAGE: Q. Dr. Weisberg, I'm handing you a document that is marked D-1. Are you familiar with that document? A. Yes.	3 4 5 6 7 8 9 10 11 12 13 14 15 16	as a medical director. Q. So what did you do between what do you do now? A. I retired on August the 31st and started back as a contractor part-time for Ethicon on September 1st, and that's what I'm doing now. Q. So were you a medical director at Ethicon from 2000 through the mid part of 2015? A. Yes. Q. And what, if any, gynecological meshes were you responsible for during that timeframe? A. Throughout that period, I I participated in in almost all of the
4 5 6 7 8 9 10 11 12 13 14 15 16 17	2:04. We're back on the record. (Deposition Exhibit No. D-1, Ethicon Response to Section 39 Request and Attachments, ETH.MESH.22631022 through ETH.MESH.22632029, was marked for identification.) BY MR. GAGE: Q. Dr. Weisberg, I'm handing you a document that is marked D-1. Are you familiar with that document? A. Yes. Q. And what is that document?	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	as a medical director. Q. So what did you do between what do you do now? A. I retired on August the 31st and started back as a contractor part-time for Ethicon on September 1st, and that's what I'm doing now. Q. So were you a medical director at Ethicon from 2000 through the mid part of 2015? A. Yes. Q. And what, if any, gynecological meshes were you responsible for during that timeframe? A. Throughout that period, I I participated in in almost all of the gynecological meshes at one time or another.
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	2:04. We're back on the record. (Deposition Exhibit No. D-1, Ethicon Response to Section 39 Request and Attachments, ETH.MESH.22631022 through ETH.MESH.22632029, was marked for identification.) BY MR. GAGE: Q. Dr. Weisberg, I'm handing you a document that is marked D-1. Are you familiar with that document? A. Yes. Q. And what is that document? A. This is the response to the Health	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	as a medical director. Q. So what did you do between what do you do now? A. I retired on August the 31st and started back as a contractor part-time for Ethicon on September 1st, and that's what I'm doing now. Q. So were you a medical director at Ethicon from 2000 through the mid part of 2015? A. Yes. Q. And what, if any, gynecological meshes were you responsible for during that timeframe? A. Throughout that period, I I participated in in almost all of the gynecological meshes at one time or another. Q. Would that have included the TVT
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	2:04. We're back on the record. (Deposition Exhibit No. D-1, Ethicon Response to Section 39 Request and Attachments, ETH.MESH.22631022 through ETH.MESH.22632029, was marked for identification.) BY MR. GAGE: Q. Dr. Weisberg, I'm handing you a document that is marked D-1. Are you familiar with that document? A. Yes. Q. And what is that document? A. This is the response to the Health Canada request.	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	as a medical director. Q. So what did you do between what do you do now? A. I retired on August the 31st and started back as a contractor part-time for Ethicon on September 1st, and that's what I'm doing now. Q. So were you a medical director at Ethicon from 2000 through the mid part of 2015? A. Yes. Q. And what, if any, gynecological meshes were you responsible for during that timeframe? A. Throughout that period, I I participated in in almost all of the gynecological meshes at one time or another. Q. Would that have included the TVT family of products?
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	2:04. We're back on the record. (Deposition Exhibit No. D-1, Ethicon Response to Section 39 Request and Attachments, ETH.MESH.22631022 through ETH.MESH.22632029, was marked for identification.) BY MR. GAGE: Q. Dr. Weisberg, I'm handing you a document that is marked D-1. Are you familiar with that document? A. Yes. Q. And what is that document? A. This is the response to the Health Canada request. Q. And when you say the response, you're	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	as a medical director. Q. So what did you do between what do you do now? A. I retired on August the 31st and started back as a contractor part-time for Ethicon on September 1st, and that's what I'm doing now. Q. So were you a medical director at Ethicon from 2000 through the mid part of 2015? A. Yes. Q. And what, if any, gynecological meshes were you responsible for during that timeframe? A. Throughout that period, I I participated in in almost all of the gynecological meshes at one time or another. Q. Would that have included the TVT family of products? A. Yes.
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Page 462 Page 464 1 already been implemented; correct? 1 that. 2 2 Yes. A. The team that was responsible for 3 3 Now, sir, when -- did you work as preparing the response to the Health Canada inquiry Q. 4 4 part of a team in preparing the response to the obviously did its work in 2015, because the inquiry 5 Health Canada inquiry? 5 from Health Canada first arrived in 2015; is that 6 6 Yes, I did. A. correct? 7 7 Q. When your team began the process of A. Correct. 8 8 making changes to the various IFUs we've discussed, MR. FREESE: Object to the form of 9 was any consideration given by your team of the 9 the question. Do you mean '14? 10 number of years that these various devices had been 10 THE WITNESS: Oh --11 11 on the market? MR. FREESE: The request, was it --12 THE WITNESS: I'm sorry. The request 12 A. Yes. 13 O. Why? 13 was in March of '14. 14 14 Because it's data. It's confirmed, MR. GAGE: I'm sorry. Strike that. A. 15 published evidence, and that's really the best way 15 Let me ask the question. 16 to know how a product is behaving and interacting 16 THE WITNESS: Thank you. 17 and is being used and how successful it is. 17 BY MR. GAGE: 18 And when you talk about published 18 The work that your team did was to 19 data, what are you speaking of in particular? 19 perform -- strike it. Let me start it over. 20 20 Generally, randomized, controlled The work that your team did began in 21 studies that are published in medical journals. 21 2014 after receiving the Health Canada inquiry in 22 Q. What are randomized, controlled 22 2014; is that correct? studies? 23 23 That's correct. A. 24 24 Randomized -- we'll break that down. As of the time that your team A. Q. 25 A randomized study is one in which one group 25 prepared the response, how many years of data was Page 463 Page 465 1 receives an investigational device -- now, 1 already in existence with regard to the TVT line of 2 investigational doesn't necessarily mean that it 2 products? 3 hasn't been approved, but the device that you're 3 Well, we had studies that looked at 4 investigating in this study -- and another group has 4 women who had it in for 17 years, but the device was 5 the same procedures done with other devices or other 5 launched in 1997 and there were papers back that 6 methods and you get to -- patients are randomly 6 7 assigned into these groups to avoid bias. 7 And which device specifically are you referring to? 8 8 And you compare the results of the --9 9 of the two groups to see if one is better, worse, as That would be the TVT Retropubic. A. 10 good as the other. 10 Q. When was the TVT-O launched? 11 In 2004. 11 What is the significance, if any, of A. 12 that process as viewed by the medical and scientific 12 How many years of data did your team 13 community? 13 have available, as of the time it began working on 14 the response to the Health Canada inquiry, with A. Randomized, controlled studies are --14 15 MR. FREESE: Object to the form of 15 regard to TVT-O? 16 16 the question. A. Ten. 17 17 You can go ahead. Do you know how many randomized 18 THE WITNESS: Randomized, controlled 18 clinical trials had been performed on the TVT device 19 studies are considered the best kinds of studies 19 as of 2014 when your team was working on the 20 20 response to the Health Canada inquiry? because the same things are looked for in each 21 group, the same -- as many parameters as can be are 21 MR. FREESE: Object to the form of 22 22 the same in each group, and the only variant is the the question. device that you're testing. 23 23 THE WITNESS: On the retropubic, a 24 BY MR. GAGE: 24 little over a hundred. The obturator, a little over 25 25 The team that responded -- or strike

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1 By MR. GAGE: 2 Q. Who performed hose studies? 3 A. They were performed by a number of people independently. There were some studies that were funded by Ethicon, but most were not. 4 Q. How many women were involved collectively in these studies? 5 A. Thousands. I don't have an exact number. 6 Q. Now, you talk about the studies being published. Where were these studies that contain this data published? 10 Q. Now, you talk about the studies being published. Where were these studies that contain this data published? 11 Is a funded a published? 12 It is data published? 13 A. In medical journals. 14 Q. And just help us understand what are then verted by an editorial board who reviews a medical journals are. 15 publications, to which people submit articles that are then verted by an editorial board who reviews in investigative technique; and then it's decided by the articles for the content, the statistics, the investigative technique; and then it's decided by the articles for the content, the statistics, the investigative technique; and then it's decided by the articles for the content, the statistics, the investigative technique; and then it's decided by the articles for the content, the statistics, the investigative technique; and then it's decided by the articles for the content, the statistics, the investigative technique; and then it's decided by the articles for the content, the statistics, the investigative technique; and then it's decided by that medical board – by that editorial board whether an article is worthy of publication. 23 Q. Putting aside randomized clinical trials, were there other kinds of studies that had been performed on TVT and TVT-O at the time your says, see, Ive done this many of these procedures, 1 and 1		Page 466		Page 468
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Page 470 Page 472 1 it was going through the analysis of the TVT IFUs as 1 practice to make that record or document? 2 2 to what doctors may have already known or didn't Yes. A. 3 3 already know about the substance of the 2015 Q. Now, sir, if you look under the 4 4 changes? purpose paragraph there, it says to comply with 5 MR. FREESE: Object to the form of 5 request from Health Canada to align with the FDA 6 6 proposed rules and to align with internal standards, the question. 7 7 change project, certain number, will revise IFUs of THE WITNESS: Yes. 8 8 products in the TVT product family. This memo BY MR. GAGE: 9 What were those conclusions? 9 serves as the initial product risk assessment O. 10 For the most part -- for the most 10 evaluating the impact of this change. Α. 11 11 part, the conversations that I personally had and Do you see that? that we had during our validations of the new IFU 12 12 A. Yes. 13 was that this is not really new information. 13 O. And then we go further down and it 14 And why is that? 14 O. says assessment. 15 A. The device is used for the treatment 15 Yes. Α. Now, this document pertains to the 16 of urinary incontinence. Most of the warnings, most 16 Q. 17 of the adverse events, are events that happened with 17 changes to the IFU that were being made in response 18 any method of trying to treat urinary stress 18 to Health Canada; correct? 19 incontinence, and the surgeons who were using this 19 Yes. A. 20 20 understood that for the most part. O. We go further down and it says, 21 The other piece of it was that this 21 assessment: Per the design change notice for this 22 was a mesh product, and doctors understand what can 22 project, the proposed IFU changes consist of 23 enhancing the current IFUs to better describe known 23 happen when you put mesh in. MR. FREESE: Move to strike; 24 product risks or to include hazards not currently 24 nonresponsive. 25 25 identified in the IFUs. Page 471 Page 473 1 BY MR. GAGE: 1 Do you see that? 2 2 Yes. Dr. Weisberg, I'm handing you a A. 3 document that's been previously marked as P-1635. 3 O. What does that mean? 4 4 Are you familiar with this document? MR. FREESE: Object to the form of 5 5 A. I am. the question. 6 Q. This appears to be a memo from Lee 6 THE WITNESS: Well, there is a -- a 7 7 Hackman to the project file, and the subject says procedure that we need to follow when we make these 8 8 initial product risk assessment for IFU change changes to see if they were included in the previous 9 9 project for TVT products, and it's dated September risk documents that we created, and one of the 10 19, 2014; correct? 10 things that it looks for is to make sure that all 11 11 the identified harms are addressed in those risk A. Correct. 12 Are you familiar with this document? 12 documents and that to see whether there are any Q. 13 13 things in the IFU that haven't been addressed. A. 14 14 Was this document created by a member BY MR. GAGE: 15 of your team that was working on the Health Canada 15 So we go to the next paragraph and it 16 response? 16 says, a review of the risk assessment summaries for 17 TVT and TVT Exact and for TVT Obturator and TVT 17 A. Yes. 18 18 Abbrevo, as well as the corresponding clinical O. Was this a writing made at or near evaluation report for TVT products, confirms that 19 the time of the events described in the document by 19 20 a person or persons with actual knowledge? 20 all identified harms are adequately addressed in 21 A. Yes. 21 current risk management documents and that the 22 22 Q. Was the writing made in the regular proposed IFU changes introduce no new design or course of Ethicon's business? 23 user-related risks, nor increase any risk levels. 23 24 A. 24 Do you see that? 25 25 That's true. Was it Ethicon's regular business Q. A.

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Page 474 Page 476 1 What does it mean when the sentence 1 to those concepts? 2 2 says, a review of the risk assessment summaries MR. FREESE: Object to the form of 3 3 confirms that all identified harms are adequately the question. 4 addressed in current risk management documents? 4 THE WITNESS: That the ones that were 5 MR. FREESE: Object to the form of 5 in these files remained accurate and honest and none 6 6 had to be changed. the question. 7 7 THE WITNESS: Risk management MR. FREESE: Move to strike as 8 8 documents include, among other things, failure mode nonresponsive. 9 analyses, design failure mode analyses, production 9 10 failure mode analyses, the users -- things that 10 (Deposition Exhibit No. D-2, 7/29/14 11 11 could go wrong when the user uses the device, CAPA-003474, ETH.MESH.22625140 through 12 application failure mode analyses. 12 ETH.MESH.22625145, was marked for 13 13 And for every one of those failure identification.) 14 modes, anything that could go wrong, we assess what 14 15 the severity of that might be, does it require no 15 BY MR. GAGE: 16 treatment, does a patient die, and everything in 16 Dr. Weisberg, I'm now handing you a 17 between are all given numbers. 17 document marked D-2. Do you see this document? 18 And then we assess the frequency of 18 19 these failure modes and how often they are --19 Are you familiar with this document? O. 20 20 initially, when a device first comes out, how often Α. I am. 21 they are expected to happen and then as they are 21 Q. Is this document, was it created in 22 reviewed, how often do they actually happen. 22 connection with the response to Health Canada? 23 So you have frequency and severity of 23 A. each hazard and the harm that it may create. 24 24 Q. What is this document? 25 25 BY MR. GAGE: Α. This is a CAPA report and --Page 475 Page 477 1 O. And what did that review conclude 1 Q. Let me stop you there. What is a 2 with regard to the changes being made in response to 2 CAPA report? 3 3 the Health Canada inquiry? It's a corrective action -- oh, I Α. 4 MR. FREESE: Object to the form of 4 always forget the --5 5 the question. Q. Is it pre --6 THE WITNESS: Everything in the 6 A. Corrective and preventative action --7 changes were previously addressed in these failure 7 All right. Q. 8 8 mode analyses. -- report and if something comes up 9 9 that sounds like it might need a corrective or MR. FREESE: Move to strike as 10 nonresponsive. 10 preventative action, a CAPA is established and BY MR. GAGE: 11 investigation is done to see if or whether or what 11 12 may need to be modified to address the issue. 12 The sentence then goes on: The 13 proposed IFU changes introduce no new design or 13 All right. On the first page, it 14 user-related risks, nor increase any risk levels. 14 says the CAPA was created July 29, 2014. Do you see 15 What does that mean? 15 that? 16 MR. FREESE: Object to the form of 16 A. I see that. 17 17 Q. Was this a writing that was made at the question. or near the time of the events described in the 18 18 THE WITNESS: Well, new design or user-related risks would be additional things in the 19 19 document by a person or persons with actual 20 hazard column of this report, and the risk levels 20 knowledge? 21 would -- would -- the risk level's a summary of the 21 A. 22 severity and the frequency. 22 Q. Was this writing made in the regular BY MR. GAGE: 23 course of Ethicon's business? 23 24 24 And what was the conclusion, if any, A. of the review of the risk of summaries with regard 25 25 Q. And was it Ethicon's regular business

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	Page 478		Page 480
1	practice to make this sort of record or document?	1	the question.
2	A. Yes.	2	THE WITNESS: It was my opinion
3	Q. Sir, on the first page, we see in the	3	because upon reading it, I felt that anyone who knew
4	middle, it says: This CAPA was open to address the	4	how to do this procedure would know who to choose to
5	labeling updates that will be made to the TVT,	5	do it who to choose to do it on, who not to do it
6	Gynemesh, and Artisyn product families to address	6	on, exactly how to do it, and there would have been
7	the Health Canada Section 39 request.	7	none of the well, let me just stop it there.
8	Do you see that?	8	BY MR. GAGE:
9	A. I see that.	9	Q. All right.
10	Q. And that's the team that you were the	10	It says it says, although perhaps
11	medical director for; correct?	11	they were not articulated in the manner and to the
12	A. Yes.	12	degree requested by Health Canada. Do you see that?
13	Q. On the next page, ETH.MESH.22625141,	13	A. I do.
14	in the middle of the page, we see a paragraph that	14	Q. What did that mean?
15	begins: According to the health hazard evaluation,	15	MR. FREESE: Object to the form of
16	HHE, documented in PRE14-0055S, no immediate or	16	the question.
17	long-range health consequences that may result from	17	THE WITNESS: Judging by their
18	use of or exposure to the products are expected.	18	suggestions, they wanted some very basic,
19	The safety and effectiveness of the devices have not	19	well-known, well understood facts to be put into the
20	changed. The existing labels were adequate to	20	IFU, which were just so well-known in the surgical
21	provide instructions for use including warnings and	21	community that they weren't necessarily they
22	precautions, and the proposed new labels clarify and	22	weren't necessary to be there.
23	expand on information currently contained within the	23	MR. FREESE: Move to strike as
24	labeling. According to the medical director, quote,	24	nonresponsive.
25	it is my medical opinion that the existing labels	25	
	Page 479		Page 481
1	were adequate to provide instructions for use	1	(Deposition Exhibit No. D-3, 2008 TVT
2	including warnings and precautions, although perhaps	2	Brochure, ETH.MESH.08003279 through
3	they were not articulated in the manner and to the	3	ETH.MESH.08003294, was marked for
4	degree requested by Health Canada. Changes will be	4	identification.)
5	made to generally refresh the labels and satisfy	5	
6	requests made by Health Canada, close quote.	6	BY MR. GAGE:
7	Do you see that?	7	Q. Sir, I'm handing you a document
8	A. I do.	8	marked D-3. Are you familiar with this document,
9	Q. It says according to the medical	9	sir?
10	director. Who is that person?	10	A. Yes, I am.
11	A. That would have been me.	11	Q. And what is this document?
12	Q. Are those your words	12	A. This is a patient brochure.
13	A. Oh. I believe these are my words and	13	Q. And I think if we go over to the last
14	I believe that was me, yes.	14	page, the very last page near the bottom
15	Q. And that the words would be what's	15	A. Yes.
16	inside the quotations; correct?	16	Q it says Ethicon, Inc. 2008. Do
17	A. Yes.	17	you see that?
18	Q. Now, it says, it's my medical opinion	18	A. Yes.
19	that the existing labels were adequate to provide	19	Q. And then it says TVT016R9. What is
20	instructions for use including warnings and	20	that number?
21	precautions.	21	A. It's a copy review number.
22	Do you see that?	22	Q. And what's the significance, if any,
23	A. Yes.	23	of that?
24	Q. Why was that your opinion?	24	A. Everything that goes out of Ethicon
25	MR. FREESE: Object to the form of	25	to customers or to patients needs to be reviewed by

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	Page 482		Page 484
1	medical, legal, and regulatory for accuracy, and	1	the time of the events described in the document by
2	that's done by a copy review team; and each of these	2	persons or a team with actual knowledge?
3	has a number and that's how you can reference that	3	A. Yes.
4	it was approved.	4	Q. And was this writing made in the
5	Q. All right. And is this a patient	5	regular course of Ethicon's business?
6	brochure?	6	A. Yes.
7	A. It is a patient brochure.	7	Q. And was it Ethicon's regular business
8	Q. For the TVT family of products?	8	practice to make those types of records or
9	A. Yes.	9	documents?
10	Q. Sir, if you would, turn with me to	10	A. Yes.
11	page 10 I'm sorry page page 13.	11	Q. All right.
12	A. (Witness complies.)	12	Sir, I've handed you another
13	Q. Are you at the place where it says:	13	document. It's marked D-4. Do you see that?
14	What are the risks?	14	A. Yes.
15	A. Yes.	15	Q. And if you would, what is this
16	Q. It says: All surgical complications	16	document?
17	present some risks. Complications associated with	17	A. This is also a patient brochure.
18	the procedure include injury to blood vessels of the	18	Q. All right.
19	pelvis, difficulty urinating, pain, scarring, pain	19	And we see at the very bottom on the
20	with intercourse, bladder, and bowel injury.	20	first page, Ethicon, Inc. 2012 and then we see over
21	There's also a risk of the mesh material becoming	21	to the right, TVT-375-12.
22	exposed. Exposure may require treatment. For a	22	Do you see that?
23	complete description of risks, see the attached	23	A. Yes yes.
24	product information. Synthetic mesh is a permanent	24	Q. And would that be a copy review
25	medical device implant; therefore, you should	25	number?
	- 400		
	Page 483		Page 485
1		1	
1 2	carefully discuss the decision to have surgery with	1 2	A. Yes.
2	carefully discuss the decision to have surgery with your doctor and understand the benefits and risks of	2	A. Yes.Q. And, sir, again, this is a patient
2	carefully discuss the decision to have surgery with your doctor and understand the benefits and risks of mesh implant surgery before deciding how to treat	2	A. Yes.Q. And, sir, again, this is a patientbrochure for the TVT family of products; is that
2 3 4	carefully discuss the decision to have surgery with your doctor and understand the benefits and risks of mesh implant surgery before deciding how to treat your condition.	2 3 4	A. Yes. Q. And, sir, again, this is a patient brochure for the TVT family of products; is that correct?
2 3 4 5	carefully discuss the decision to have surgery with your doctor and understand the benefits and risks of mesh implant surgery before deciding how to treat your condition. Do you see that?	2 3 4 5	 A. Yes. Q. And, sir, again, this is a patient brochure for the TVT family of products; is that correct? A. It is.
2 3 4 5 6	carefully discuss the decision to have surgery with your doctor and understand the benefits and risks of mesh implant surgery before deciding how to treat your condition. Do you see that? A. Yes.	2 3 4 5 6	 A. Yes. Q. And, sir, again, this is a patient brochure for the TVT family of products; is that correct? A. It is. Q. And if you would, sir, please turn to
2 3 4 5 6 7	carefully discuss the decision to have surgery with your doctor and understand the benefits and risks of mesh implant surgery before deciding how to treat your condition. Do you see that? A. Yes. Q. What is the significance, if any, of	2 3 4 5 6 7	A. Yes. Q. And, sir, again, this is a patient brochure for the TVT family of products; is that correct? A. It is. Q. And if you would, sir, please turn to the last piece of paper in this exhibit.
2 3 4 5 6 7 8	carefully discuss the decision to have surgery with your doctor and understand the benefits and risks of mesh implant surgery before deciding how to treat your condition. Do you see that? A. Yes. Q. What is the significance, if any, of the risks contained in this 2008 patient brochure in	2 3 4 5 6 7 8	 A. Yes. Q. And, sir, again, this is a patient brochure for the TVT family of products; is that correct? A. It is. Q. And if you would, sir, please turn to the last piece of paper in this exhibit. A. (Witness complies.)
2 3 4 5 6 7 8	carefully discuss the decision to have surgery with your doctor and understand the benefits and risks of mesh implant surgery before deciding how to treat your condition. Do you see that? A. Yes. Q. What is the significance, if any, of the risks contained in this 2008 patient brochure in the context of the information that Health Canada	2 3 4 5 6 7 8	A. Yes. Q. And, sir, again, this is a patient brochure for the TVT family of products; is that correct? A. It is. Q. And if you would, sir, please turn to the last piece of paper in this exhibit. A. (Witness complies.) Q. And there's a title a heading
2 3 4 5 6 7 8 9	carefully discuss the decision to have surgery with your doctor and understand the benefits and risks of mesh implant surgery before deciding how to treat your condition. Do you see that? A. Yes. Q. What is the significance, if any, of the risks contained in this 2008 patient brochure in the context of the information that Health Canada was asking you to include in your IFUs?	2 3 4 5 6 7 8 9	A. Yes. Q. And, sir, again, this is a patient brochure for the TVT family of products; is that correct? A. It is. Q. And if you would, sir, please turn to the last piece of paper in this exhibit. A. (Witness complies.) Q. And there's a title a heading there that says what are the risks. Do you see
2 3 4 5 6 7 8 9 10 11	carefully discuss the decision to have surgery with your doctor and understand the benefits and risks of mesh implant surgery before deciding how to treat your condition. Do you see that? A. Yes. Q. What is the significance, if any, of the risks contained in this 2008 patient brochure in the context of the information that Health Canada was asking you to include in your IFUs? MR. FREESE: Object to the form of	2 3 4 5 6 7 8 9 10	A. Yes. Q. And, sir, again, this is a patient brochure for the TVT family of products; is that correct? A. It is. Q. And if you would, sir, please turn to the last piece of paper in this exhibit. A. (Witness complies.) Q. And there's a title a heading there that says what are the risks. Do you see that?
2 3 4 5 6 7 8 9 10 11	carefully discuss the decision to have surgery with your doctor and understand the benefits and risks of mesh implant surgery before deciding how to treat your condition. Do you see that? A. Yes. Q. What is the significance, if any, of the risks contained in this 2008 patient brochure in the context of the information that Health Canada was asking you to include in your IFUs? MR. FREESE: Object to the form of the question.	2 3 4 5 6 7 8 9 10 11	A. Yes. Q. And, sir, again, this is a patient brochure for the TVT family of products; is that correct? A. It is. Q. And if you would, sir, please turn to the last piece of paper in this exhibit. A. (Witness complies.) Q. And there's a title a heading there that says what are the risks. Do you see that? A. Yes.
2 3 4 5 6 7 8 9 10 11 12 13	carefully discuss the decision to have surgery with your doctor and understand the benefits and risks of mesh implant surgery before deciding how to treat your condition. Do you see that? A. Yes. Q. What is the significance, if any, of the risks contained in this 2008 patient brochure in the context of the information that Health Canada was asking you to include in your IFUs? MR. FREESE: Object to the form of the question. THE WITNESS: A good deal of it is	2 3 4 5 6 7 8 9 10	A. Yes. Q. And, sir, again, this is a patient brochure for the TVT family of products; is that correct? A. It is. Q. And if you would, sir, please turn to the last piece of paper in this exhibit. A. (Witness complies.) Q. And there's a title a heading there that says what are the risks. Do you see that? A. Yes. Q. It says, risks common to all pelvic
2 3 4 5 6 7 8 9 10 11	carefully discuss the decision to have surgery with your doctor and understand the benefits and risks of mesh implant surgery before deciding how to treat your condition. Do you see that? A. Yes. Q. What is the significance, if any, of the risks contained in this 2008 patient brochure in the context of the information that Health Canada was asking you to include in your IFUs? MR. FREESE: Object to the form of the question.	2 3 4 5 6 7 8 9 10 11 12 13 14	A. Yes. Q. And, sir, again, this is a patient brochure for the TVT family of products; is that correct? A. It is. Q. And if you would, sir, please turn to the last piece of paper in this exhibit. A. (Witness complies.) Q. And there's a title a heading there that says what are the risks. Do you see that? A. Yes. Q. It says, risks common to all pelvic surgeries: Risks for all pelvic surgeries include
2 3 4 5 6 7 8 9 10 11 12 13 14	carefully discuss the decision to have surgery with your doctor and understand the benefits and risks of mesh implant surgery before deciding how to treat your condition. Do you see that? A. Yes. Q. What is the significance, if any, of the risks contained in this 2008 patient brochure in the context of the information that Health Canada was asking you to include in your IFUs? MR. FREESE: Object to the form of the question. THE WITNESS: A good deal of it is within those two paragraphs.	2 3 4 5 6 7 8 9 10 11 12 13	A. Yes. Q. And, sir, again, this is a patient brochure for the TVT family of products; is that correct? A. It is. Q. And if you would, sir, please turn to the last piece of paper in this exhibit. A. (Witness complies.) Q. And there's a title a heading there that says what are the risks. Do you see that? A. Yes. Q. It says, risks common to all pelvic surgeries: Risks for all pelvic surgeries include pain with intercourse, pelvic pain, development of
2 3 4 5 6 7 8 9 10 11 12 13 14 15	carefully discuss the decision to have surgery with your doctor and understand the benefits and risks of mesh implant surgery before deciding how to treat your condition. Do you see that? A. Yes. Q. What is the significance, if any, of the risks contained in this 2008 patient brochure in the context of the information that Health Canada was asking you to include in your IFUs? MR. FREESE: Object to the form of the question. THE WITNESS: A good deal of it is within those two paragraphs.	2 3 4 5 6 7 8 9 10 11 12 13 14 15	A. Yes. Q. And, sir, again, this is a patient brochure for the TVT family of products; is that correct? A. It is. Q. And if you would, sir, please turn to the last piece of paper in this exhibit. A. (Witness complies.) Q. And there's a title a heading there that says what are the risks. Do you see that? A. Yes. Q. It says, risks common to all pelvic surgeries: Risks for all pelvic surgeries include pain with intercourse, pelvic pain, development of urinary incontinence or voiding difficulties,
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	carefully discuss the decision to have surgery with your doctor and understand the benefits and risks of mesh implant surgery before deciding how to treat your condition. Do you see that? A. Yes. Q. What is the significance, if any, of the risks contained in this 2008 patient brochure in the context of the information that Health Canada was asking you to include in your IFUs? MR. FREESE: Object to the form of the question. THE WITNESS: A good deal of it is within those two paragraphs. (Deposition Exhibit No. D-4, 2012 TVT Brochure, ETH.MESH.09744858 through	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	A. Yes. Q. And, sir, again, this is a patient brochure for the TVT family of products; is that correct? A. It is. Q. And if you would, sir, please turn to the last piece of paper in this exhibit. A. (Witness complies.) Q. And there's a title a heading there that says what are the risks. Do you see that? A. Yes. Q. It says, risks common to all pelvic surgeries: Risks for all pelvic surgeries include pain with intercourse, pelvic pain, development of urinary incontinence or voiding difficulties, hemorrhage, bleeding or hematoma, collections of
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	carefully discuss the decision to have surgery with your doctor and understand the benefits and risks of mesh implant surgery before deciding how to treat your condition. Do you see that? A. Yes. Q. What is the significance, if any, of the risks contained in this 2008 patient brochure in the context of the information that Health Canada was asking you to include in your IFUs? MR. FREESE: Object to the form of the question. THE WITNESS: A good deal of it is within those two paragraphs. (Deposition Exhibit No. D-4, 2012 TVT Brochure, ETH.MESH.09744858 through ETH.MESH.09744863, was marked for	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	A. Yes. Q. And, sir, again, this is a patient brochure for the TVT family of products; is that correct? A. It is. Q. And if you would, sir, please turn to the last piece of paper in this exhibit. A. (Witness complies.) Q. And there's a title a heading there that says what are the risks. Do you see that? A. Yes. Q. It says, risks common to all pelvic surgeries: Risks for all pelvic surgeries include pain with intercourse, pelvic pain, development of urinary incontinence or voiding difficulties, hemorrhage, bleeding or hematoma, collections of blood in the pelvis, injury to abdominal organs
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	carefully discuss the decision to have surgery with your doctor and understand the benefits and risks of mesh implant surgery before deciding how to treat your condition. Do you see that? A. Yes. Q. What is the significance, if any, of the risks contained in this 2008 patient brochure in the context of the information that Health Canada was asking you to include in your IFUs? MR. FREESE: Object to the form of the question. THE WITNESS: A good deal of it is within those two paragraphs. (Deposition Exhibit No. D-4, 2012 TVT Brochure, ETH.MESH.09744858 through	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	A. Yes. Q. And, sir, again, this is a patient brochure for the TVT family of products; is that correct? A. It is. Q. And if you would, sir, please turn to the last piece of paper in this exhibit. A. (Witness complies.) Q. And there's a title a heading there that says what are the risks. Do you see that? A. Yes. Q. It says, risks common to all pelvic surgeries: Risks for all pelvic surgeries include pain with intercourse, pelvic pain, development of urinary incontinence or voiding difficulties, hemorrhage, bleeding or hematoma, collections of blood in the pelvis, injury to abdominal organs including bowel, urinary tract infection, bladder
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	carefully discuss the decision to have surgery with your doctor and understand the benefits and risks of mesh implant surgery before deciding how to treat your condition. Do you see that? A. Yes. Q. What is the significance, if any, of the risks contained in this 2008 patient brochure in the context of the information that Health Canada was asking you to include in your IFUs? MR. FREESE: Object to the form of the question. THE WITNESS: A good deal of it is within those two paragraphs. (Deposition Exhibit No. D-4, 2012 TVT Brochure, ETH.MESH.09744858 through ETH.MESH.09744863, was marked for identification.)	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. Yes. Q. And, sir, again, this is a patient brochure for the TVT family of products; is that correct? A. It is. Q. And if you would, sir, please turn to the last piece of paper in this exhibit. A. (Witness complies.) Q. And there's a title a heading there that says what are the risks. Do you see that? A. Yes. Q. It says, risks common to all pelvic surgeries: Risks for all pelvic surgeries include pain with intercourse, pelvic pain, development of urinary incontinence or voiding difficulties, hemorrhage, bleeding or hematoma, collections of blood in the pelvis, injury to abdominal organs including bowel, urinary tract infection, bladder injury, wound healing problems, fistula, holes
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	carefully discuss the decision to have surgery with your doctor and understand the benefits and risks of mesh implant surgery before deciding how to treat your condition. Do you see that? A. Yes. Q. What is the significance, if any, of the risks contained in this 2008 patient brochure in the context of the information that Health Canada was asking you to include in your IFUs? MR. FREESE: Object to the form of the question. THE WITNESS: A good deal of it is within those two paragraphs. (Deposition Exhibit No. D-4, 2012 TVT Brochure, ETH.MESH.09744858 through ETH.MESH.09744863, was marked for identification.)	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	A. Yes. Q. And, sir, again, this is a patient brochure for the TVT family of products; is that correct? A. It is. Q. And if you would, sir, please turn to the last piece of paper in this exhibit. A. (Witness complies.) Q. And there's a title a heading there that says what are the risks. Do you see that? A. Yes. Q. It says, risks common to all pelvic surgeries: Risks for all pelvic surgeries include pain with intercourse, pelvic pain, development of urinary incontinence or voiding difficulties, hemorrhage, bleeding or hematoma, collections of blood in the pelvis, injury to abdominal organs including bowel, urinary tract infection, bladder injury, wound healing problems, fistula, holes between bladder or bowel and the vagina, injury to
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	carefully discuss the decision to have surgery with your doctor and understand the benefits and risks of mesh implant surgery before deciding how to treat your condition. Do you see that? A. Yes. Q. What is the significance, if any, of the risks contained in this 2008 patient brochure in the context of the information that Health Canada was asking you to include in your IFUs? MR. FREESE: Object to the form of the question. THE WITNESS: A good deal of it is within those two paragraphs. (Deposition Exhibit No. D-4, 2012 TVT Brochure, ETH.MESH.09744858 through ETH.MESH.09744863, was marked for identification.) BY MR. GAGE: Q. Sir, I'm handing you a document	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. Yes. Q. And, sir, again, this is a patient brochure for the TVT family of products; is that correct? A. It is. Q. And if you would, sir, please turn to the last piece of paper in this exhibit. A. (Witness complies.) Q. And there's a title a heading there that says what are the risks. Do you see that? A. Yes. Q. It says, risks common to all pelvic surgeries: Risks for all pelvic surgeries include pain with intercourse, pelvic pain, development of urinary incontinence or voiding difficulties, hemorrhage, bleeding or hematoma, collections of blood in the pelvis, injury to abdominal organs including bowel, urinary tract infection, bladder injury, wound healing problems, fistula, holes between bladder or bowel and the vagina, injury to ureters, tubes bringing urine from kidneys to
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49 (Pages 482 to 485)

	Page 486		Page 488
1	Q. Beneath that, it says, complications	1	Q. Was the writing made in the regular
2	associated with synthetic mesh: There is a risk of	2	course of Ethicon's business?
3	the mesh material becoming exposed into the vagina.	3	A. Yes.
4	Mesh exposure can be associated with pain during	4	Q. And was it Ethicon's regular business
5	intercourse for you and your partner. Exposure may	5	practice to make records and documents of this type?
6	require treatment, such as vaginal medication or	6	A. Yes.
7	removal of the exposed mesh, which may be performed	7	
8	in the office or operating room. There's a risk of	8	(Deposition Exhibit No. D-5, 1/15
9	infection, inflammation, vaginal scarring, and mesh	9	E-Mail Chain, ETH.MESH.22631008, was
10	contracture, mesh shortening due to scar tissue.	10	marked for identification.)
11	Pelvic pain or pain with intercourse may occur and	11	
12	may resolve with time. There is a risk of	12	BY MR. GAGE:
13	developing urinary incontinence or difficulty	13	Q. I'm handing you a document marked
14	urinating. Synthetic mesh is a permanent medical	14	D-5, and this appears to be an e-mail; is that
15	device implant; therefore, you should carefully	15	correct?
16	discuss the decision to have surgery with your	16	A. Series of e-mails.
17	surgeon and understand the benefits and risks of	17	Q. Series of e-mails. It's from
18	mesh implant surgery before deciding how to treat	18	reading from the top of the document down, it's from
19	your condition.	19	Stacy Kluesner to Becky Robinson and others, dated
20	Did I read that correctly?	20	January 21, 2015.
21	A. Yes.	21	Do you see that?
22	Q. Did the Health Canada team, as it was	22	A. That's correct, yes.
23	contemplating the requests from Health Canada, take	23	Q. And who is Stacy Kluesner?
24	into account any of the information in this patient	24	A. Stacy Kluesner is the regulatory
25	brochure?	25	representative working on the Health Canada project.
	Page 487		Page 489
1	A. Yes.	1	Q. And so she was one of your team
2	MR. BARLOW: Object to the form and	2	members?
3	foundation.	3	A. Yes.
4	MR. FREESE: Object to the form of	4	Q. Did you work with her in preparing
5	the question.	5	the response to Health Canada?
6	BY MR. GAGE:	6	A. Yes.
7	Q. In what respect?	7	Q. Did you have any conversations with
8	A. We reviewed it.	8	Ms. Kluesner in preparing for your in preparing
9	MR. BARLOW: Same objection.	9	for this deposition?
10	BY MR. GAGE:	10	A. I did.
11	Q. And what is the significance, if any,	11	Q. What was the purpose of that?
12	of the conditions or risks listed in this patient	12	A. I just wanted to make sure that my
13	brochure and the requests that Health Canada had	13	timeline was accurate and that I understood all of
14	made of the company?	14	her correspondence that I had access to and that I
15	MR. FREESE: Object to the form of	15	I understood some of the regulatory things that
16	the question.	16	may have been happening outside of my purview.
17	THE WITNESS: Most of the the	17	Q. And was this a document that you
18	requests by Health Canada are already in the patient	18	reviewed in preparation for your deposition today?
19	brochure.	19	A. Yes.
20	BY MR. GAGE:	20	Q. And was this a writing made at or
21	Q. And was this brochure or writing made	21	near the time of the events described in the
22	at or near the time of the events described in the	22	document by a person or persons with knowledge?
23	document by a person or persons with actual	23	A. Yes.
24	knowledge?	24	Q. Was the writing made in the regular
25	A. Yes.	25	course of Ethicon's business?

50 (Pages 486 to 489)

	Page 490		Page 492
1	A. Yes.	1	our final document on what we were going to send to
2	Q. And was it Ethicon's regular business	2	Health Canada and the changes we were going to make
3	practice to make records or documents of this type?	3	in our IFU, we decided that we should make these
4	A. Yes.	4	changes universally or globally.
5	Q. We see if we kind of read from the	5	And Stacy called the FDA to discuss
6	bottom up, we see the there's an e-mail well,	6	these changes that we were going to make and get
7	from the very bottom, there's a Cisco Unity	7	their blessings that it would be either an
8	Connection Messaging System to	8	add-to-file or whether it would need a 510(k)
9	ehb@fdsla04029.fda.hhs.gov.	9	application.
10	Do you see that?	10	BY MR. GAGE:
11	A. I do.	11	Q. Did FDA first contact Ethicon about
12	Q. And the subject is message from	12	making changes to the IFUs in the TVT brochures or
13	unknown sender. Do you see that?	13	did Ethicon first contact FDA about the changes?
14	A. Yes.	14	MR. FREESE: Object to the form of
15	Q. Do you understand this to be a voice	15	the question. You gotta give me a chance to
16	mail?	16	interject.
17	A. I do.	17	THE WITNESS: I'm sorry.
18	Q. And it's dated Monday, January 19,	18	MR. FREESE: So the court reporter
19	2015; correct?	19	can get the order correctly.
20	A. Yes.	20	THE WITNESS: I'm sorry.
21	Q. And then we go above and we see an	21	MR. FREESE: That's okay.
22	e-mail from Elaine Blyskun	22	THE WITNESS: Ethicon made the first
23	A. Yes.	23	request to FDA, not the other way around.
24	Q at FDA to Stacy Kluesner. Do you	24	BY MR. GAGE:
25	see that?	25	Q. At any time, did FDA ask Ethicon to
	Page 491		Page 493
1	A. Yes.	1	implement the Health Canada changes in the United
2	A. Yes.Q. And it says: Hi, Stacy. I'm sorry	2	implement the Health Canada changes in the United States?
2	A. Yes. Q. And it says: Hi, Stacy. I'm sorry that I missed your call. I'm currently on detail to	l .	implement the Health Canada changes in the United States? MR. FREESE: Object to the form of
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	Page 494		Page 496
1	changes?	1	IFUs as they were and as we intend to change them.
2	A. No.	2	And they were submitted to the FDA for examination.
3		3	Q. And when you say redlined documents,
4	(Deposition Exhibit No. D-6, 4/8/15	4	what do you mean by redlined?
5	Cover Letter from Kluesner Attaching	5	A. Well, on a computer, if you delete
6	Add-To-File Submission, etc., Beginning	6	something, the red line goes through it to delete it
7	with ETH.MESH.22617620, was marked for	7	and if you add something, a red line goes under that
8	identification.)	8	addition, so you can readily look at it and see what
9		9	was deleted and what was added.
10	BY MR. GAGE:	10	Q. And what was the purpose of sending
11	Q. Dr. Weisberg, at some point in time,	11	these to the of your team sending these to the
12	did Ethicon provide any documentation to FDA about	12	FDA?
13	the proposed changes to the IFUs and brochures in	13	A. We wanted them to know what kind of
14	the United States?	14	changes we were intending to make.
15	A. Yes.	15	
16	Q. Dr. Weisberg, I'm handing you a	16	(Deposition Exhibit No. D-7, E-Mail
17	document that's been marked as D-6. Take just a	17	Chain and Attachments, Beginning with
18	minute and look at that.	18	ETH.MESH.22865906, was marked for
19	A. (Witness complies.) Okay.	19	identification.)
20	Q. Now, Doctor, what is collectively	20	DVAM CACE
21	marked as D-6 is one, two, three, four, five, six	21	BY MR. GAGE:
22	different separately stapled groups of documents;	22	Q. Dr. Weisberg, I'm handing you a
23	correct?	23 24	document marked D-7. Are you familiar with this
24 25	A. Yes.	25	document?
_∠5	Q. And the first one is dated April 8,	45	A. I am.
	Page 495		Page 497
1	Page 495 2015 and the re line is add-to-file submission,	1	Q. And this is a chain of e-mails which
2		2	Q. And this is a chain of e-mails which on the first page at the top is from Stacy Kluesner
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17 redlining was done manually, I believe by Stacy 18 Kluesner, to show the changes. 19 Q. And the redline changes, were those 20 changes Stacy herself thought up or were these 21 changes that the team put together? 22 A. These were changes that the team came 23 up with. 24 Q. And in each of these, the FDA what 19 is the FDA doing in these various paragraphs? 20 A. They're making suggestions on how 21 these might be edited or changed from what we sent 22 in. 23 Q. And number 1, it says: The physician 24 labeling includes two categories of risks, adverse	2 3 4 5 6 7 8 9 10 11 12 13 14	And we see handwritten changes throughout this document. A. Yes. Q. Correct? A. Correct. Q. And then at the back, we seeactually 242 ETH.MESH.24255186 A. Yes. Q we see a typed sheet. Do you see that? A. Yes. Q. All right. And what are these handwritten changes?	2 3 4 5 6 7 8 9 10 11 12 13	urogynecologic surgical mesh, dated June 4, 2015. Do you see that? A. Yes. Q. Are you familiar with this document? A. I am. Q. Did you did you discuss it with Stacy Kluesner? A. I did. Q. In preparation for your deposition? A. I did. Q. And, generally, what is this document? A. This is a response from the FDA with some suggestions for the new labeling.
18 Kluesner, to show the changes. 19 Q. And the redline changes, were those 20 changes Stacy herself thought up or were these 21 changes that the team put together? 22 A. These were changes that the team came 23 up with. 24 Q. And in each of these, the FDA what 19 is the FDA doing in these various paragraphs? 20 A. They're making suggestions on how 21 these might be edited or changed from what we sent 22 in. 23 Q. And number 1, it says: The physician 24 labeling includes two categories of risks, adverse	2 3 4 5 6 7 8 9 10 11 12 13 14 15	And we see handwritten changes throughout this document. A. Yes. Q. Correct? A. Correct. Q. And then at the back, we see actually 242 ETH.MESH.24255186 A. Yes. Q we see a typed sheet. Do you see that? A. Yes. Q. All right. And what are these handwritten changes? A. Well, the patient brochure was a	2 3 4 5 6 7 8 9 10 11 12 13 14 15	urogynecologic surgical mesh, dated June 4, 2015. Do you see that? A. Yes. Q. Are you familiar with this document? A. I am. Q. Did you did you discuss it with Stacy Kluesner? A. I did. Q. In preparation for your deposition? A. I did. Q. And, generally, what is this document? A. This is a response from the FDA with some suggestions for the new labeling. Q. All right. So we go down to number
19 Q. And the redline changes, were those 20 changes Stacy herself thought up or were these 21 changes that the team put together? 22 A. These were changes that the team came 23 up with. 24 Q. And you were involved in those 29 is the FDA doing in these various paragraphs? 20 A. They're making suggestions on how 21 these might be edited or changed from what we sent 22 in. 23 Q. And number 1, it says: The physician 24 labeling includes two categories of risks, adverse	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	And we see handwritten changes throughout this document. A. Yes. Q. Correct? A. Correct. Q. And then at the back, we see actually 242 ETH.MESH.24255186 A. Yes. Q we see a typed sheet. Do you see that? A. Yes. Q. All right. And what are these handwritten changes? A. Well, the patient brochure was a printed document that was not editable. So the	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	urogynecologic surgical mesh, dated June 4, 2015. Do you see that? A. Yes. Q. Are you familiar with this document? A. I am. Q. Did you did you discuss it with Stacy Kluesner? A. I did. Q. In preparation for your deposition? A. I did. Q. And, generally, what is this document? A. This is a response from the FDA with some suggestions for the new labeling. Q. All right. So we go down to number 1 we see number 1, 2, 3 A, B, and C; correct?
20 changes Stacy herself thought up or were these 21 changes that the team put together? 22 A. These were changes that the team came 23 up with. 24 Q. And you were involved in those 20 A. They're making suggestions on how 21 these might be edited or changed from what we sent 22 in. 23 Q. And number 1, it says: The physician 24 labeling includes two categories of risks, adverse	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	And we see handwritten changes throughout this document. A. Yes. Q. Correct? A. Correct. Q. And then at the back, we see actually 242 ETH.MESH.24255186 A. Yes. Q we see a typed sheet. Do you see that? A. Yes. Q. All right. And what are these handwritten changes? A. Well, the patient brochure was a printed document that was not editable. So the redlining was done manually, I believe by Stacy	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	urogynecologic surgical mesh, dated June 4, 2015. Do you see that? A. Yes. Q. Are you familiar with this document? A. I am. Q. Did you did you discuss it with Stacy Kluesner? A. I did. Q. In preparation for your deposition? A. I did. Q. And, generally, what is this document? A. This is a response from the FDA with some suggestions for the new labeling. Q. All right. So we go down to number 1 we see number 1, 2, 3 A, B, and C; correct? A. Yes.
21 changes that the team put together? 22 A. These were changes that the team came 23 up with. 24 Q. And you were involved in those 21 these might be edited or changed from what we sent 22 in. 23 Q. And number 1, it says: The physician 24 labeling includes two categories of risks, adverse	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	And we see handwritten changes throughout this document. A. Yes. Q. Correct? A. Correct. Q. And then at the back, we see actually 242 ETH.MESH.24255186 A. Yes. Q we see a typed sheet. Do you see that? A. Yes. Q. All right. And what are these handwritten changes? A. Well, the patient brochure was a printed document that was not editable. So the redlining was done manually, I believe by Stacy Kluesner, to show the changes.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	urogynecologic surgical mesh, dated June 4, 2015. Do you see that? A. Yes. Q. Are you familiar with this document? A. I am. Q. Did you did you discuss it with Stacy Kluesner? A. I did. Q. In preparation for your deposition? A. I did. Q. And, generally, what is this document? A. This is a response from the FDA with some suggestions for the new labeling. Q. All right. So we go down to number 1 we see number 1, 2, 3 A, B, and C; correct? A. Yes. Q. And in each of these, the FDA what
22 A. These were changes that the team came 23 up with. 24 Q. And you were involved in those 22 in. 23 Q. And number 1, it says: The physician 24 labeling includes two categories of risks, adverse	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	And we see handwritten changes throughout this document. A. Yes. Q. Correct? A. Correct. Q. And then at the back, we see actually 242 ETH.MESH.24255186 A. Yes. Q we see a typed sheet. Do you see that? A. Yes. Q. All right. And what are these handwritten changes? A. Well, the patient brochure was a printed document that was not editable. So the redlining was done manually, I believe by Stacy Kluesner, to show the changes. Q. And the redline changes, were those	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	urogynecologic surgical mesh, dated June 4, 2015. Do you see that? A. Yes. Q. Are you familiar with this document? A. I am. Q. Did you did you discuss it with Stacy Kluesner? A. I did. Q. In preparation for your deposition? A. I did. Q. And, generally, what is this document? A. This is a response from the FDA with some suggestions for the new labeling. Q. All right. So we go down to number 1 we see number 1, 2, 3 A, B, and C; correct? A. Yes. Q. And in each of these, the FDA what is the FDA doing in these various paragraphs?
23 up with. 24 Q. And you were involved in those 23 Q. And number 1, it says: The physician 24 labeling includes two categories of risks, adverse	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	And we see handwritten changes throughout this document. A. Yes. Q. Correct? A. Correct. Q. And then at the back, we see actually 242 ETH.MESH.24255186 A. Yes. Q we see a typed sheet. Do you see that? A. Yes. Q. All right. And what are these handwritten changes? A. Well, the patient brochure was a printed document that was not editable. So the redlining was done manually, I believe by Stacy Kluesner, to show the changes. Q. And the redline changes, were those changes Stacy herself thought up or were these	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	urogynecologic surgical mesh, dated June 4, 2015. Do you see that? A. Yes. Q. Are you familiar with this document? A. I am. Q. Did you did you discuss it with Stacy Kluesner? A. I did. Q. In preparation for your deposition? A. I did. Q. And, generally, what is this document? A. This is a response from the FDA with some suggestions for the new labeling. Q. All right. So we go down to number 1 we see number 1, 2, 3 A, B, and C; correct? A. Yes. Q. And in each of these, the FDA what is the FDA doing in these various paragraphs? A. They're making suggestions on how
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25 changes? 25 reactions and other adverse reactions. It is	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	And we see handwritten changes throughout this document. A. Yes. Q. Correct? A. Correct. Q. And then at the back, we see actually 242 ETH.MESH.24255186 A. Yes. Q we see a typed sheet. Do you see that? A. Yes. Q. All right. And what are these handwritten changes? A. Well, the patient brochure was a printed document that was not editable. So the redlining was done manually, I believe by Stacy Kluesner, to show the changes. Q. And the redline changes, were those changes Stacy herself thought up or were these changes that the team put together? A. These were changes that the team came up with.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	urogynecologic surgical mesh, dated June 4, 2015. Do you see that? A. Yes. Q. Are you familiar with this document? A. I am. Q. Did you did you discuss it with Stacy Kluesner? A. I did. Q. In preparation for your deposition? A. I did. Q. And, generally, what is this document? A. This is a response from the FDA with some suggestions for the new labeling. Q. All right. So we go down to number 1 we see number 1, 2, 3 A, B, and C; correct? A. Yes. Q. And in each of these, the FDA what is the FDA doing in these various paragraphs? A. They're making suggestions on how these might be edited or changed from what we sent in. Q. And number 1, it says: The physician
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53 (Pages 498 to 501)

	Page 502		Page 504
1	unclear why the risks identified as other are	1	letter.
2	categorized separately from the risks described as	2	BY MR. GAGE:
3	adverse reactions. We recommend that you revise the	3	Q. Did FDA ever ask or suggest to
4	labeling to combine both categories or explain why	4	Ethicon that a dear doctor letter was necessary?
5	the criteria used to categorize the risks into	5	A. No.
6	different categories; correct?	6	MR. FREESE: Object to the form of
7	A. Correct.	7	the question.
8	Q. And then it says for the Gynecare TVT	8	THE WITNESS: I'm sorry.
9	family of devices, we also note that voiding	9	MR. FREESE: That's okay. Don't
10	dysfunction is listed under adverse reactions, but	10	worry.
11	urge incontinence, urinary frequency, and urinary	11	THE WITNESS: Want to do it again?
12	retention, all types of voiding dysfunction, are	12	MR. FREESE: That's fine.
13	listed as other adverse reactions. We recommend	13	BY MR. GAGE:
14	that you list incontinence, urgency urinary	14	Q. Why didn't Ethicon send a dear doctor
15	frequency, and urinary retention as examples of	15	letter?
16	voiding dysfunction under adverse reactions or	16	MR. FREESE: Object to the form of
17	clarify in the physician labeling why urge	17	the question.
18	incontinence, urinary frequency, and urinary	18	THE WITNESS: Ethicon didn't feel it
19	retention are categorized separately under other	19	was necessary.
20	adverse reactions; correct?	20	BY MR. GAGE:
21	A. Correct.	21	Q. Why?
22	Q. And then paragraph 3 has various	22	A. Because the existing IFU we felt was
23	suggestions or recommendations for the patient	23	adequate, and the safety and effectiveness record of
24	labeling; correct?	24	the device really bolstered that opinion.
25	A. Yes.	25	MR. FREESE: Move to strike as
	Page 503		Page 505
1	Q. And this was a document received by	1	nonresponsive.
2	Stacy Kluesner in the course of her employment at	2	BY MR. GAGE:
3	Ethicon concerning the changes to the TVT and	3	Q. At some point, did Ethicon put the
4	Gynemesh IFUs and brochures; correct?	4	revised IFUs for the TVT family on the Ethicon
5	A. Correct.	5	website?
6		6	A. Yes.
7	(Deposition Exhibit No. D-9, Six-Page	7	Q. Can you tell us when, approximately,
8	Document Labeled "Chronology", was marked	8	that would have occurred?
9	for identification.)	9	A. Hang on. May 1st, 2015.
10	DVAM CACE	10	Q. At some point, did Ethicon begin
11	BY MR. GAGE:	11	putting the revised IFUs in the actual boxes in
12	Q. Apart from Exhibit 8, which is the	12	which the products are packaged and shipped to
13	e-mail from Sharon Andrews at FDA to Stacy Kluesner,	13	customers?
14	did FDA otherwise provide any comments to any of	14	A. Yes.
15	Ethicon's proposed changes?	15	Q. When did that occur?
16	MR. FREESE: Object to the form of	16	A. September September-October 2015.
17 18	the question. THE WITNESS: No.	17	Q. Dr. Weisberg, I'm handing you a
~	THE WITNESS: NO.	18	document that I'm marking as Exhibit 9. This is a chronology that you have referred to several times
		()	chronology that you have referred to several times
19	BY MR. GAGE:	19	
19 20	BY MR. GAGE: Q. Did FDA ever object to any of the	20	during your testimony; is that correct?
19 20 21	BY MR. GAGE: Q. Did FDA ever object to any of the changes that Ethicon proposed to the IFUs or patient	20 21	during your testimony; is that correct? A. That's correct.
19 20 21 22	BY MR. GAGE: Q. Did FDA ever object to any of the changes that Ethicon proposed to the IFUs or patient brochures?	20 21 22	during your testimony; is that correct? A. That's correct. Q. Is this a document that you helped
19 20 21 22 23	BY MR. GAGE: Q. Did FDA ever object to any of the changes that Ethicon proposed to the IFUs or patient brochures? MR. FREESE: Object to the form of	20 21 22 23	during your testimony; is that correct? A. That's correct. Q. Is this a document that you helped prepare in order for you to be prepared to testify
19 20 21 22	BY MR. GAGE: Q. Did FDA ever object to any of the changes that Ethicon proposed to the IFUs or patient brochures?	20 21 22	during your testimony; is that correct? A. That's correct. Q. Is this a document that you helped

54 (Pages 502 to 505)

	Page 506		Page 508
1	Q. Did you review the entries on this	1	Q. What are these generally?
2	timeline?	2	A. Well, this it's a letter of
3	A. I did.	3	closure from the FDA saying they've reviewed our
4	Q. Did you investigate to ensure or	4	request and basically approve it.
5	did you conduct an investigation to ensure that the	5	Q. Did FDA
6	entries are accurate and correct?	6	MR. FREESE: Move to strike as
7	A. Yes.	7	nonresponsive.
8		8	BY MR. GAGE:
9	(Deposition Exhibit No. D-10, 6/5/15	9	Q. Did FDA require you to submit a
10	E-Mails, with First One from Andrews to	10	510(k)?
11	Kluesner, ETH.MESH.22865922, was marked	11	A. They did not.
12	for identification.)	12	Q. And that would hold true with regard
13		13	to any of the devices or IFUs or patient brochures
14	BY MR. GAGE:	14	that we've been discussing?
15	Q. Dr. Weisberg, I'm handing you a	15	A. Yeah, in these applications, yes.
16	collection of e-mails from Sharon Andrews to Stacy	16	(Pause.)
17	Kluesner, all of which are dated June 5, 2015.	17	BY MR. GAGE:
18	Do you see those?	18	Q. Dr. Weisberg, I'm handing you a
19	A. Yes.	19	document that was marked yesterday as P-1638. It's
20	Q. And it says: We've reviewed the	20	the transcript of Piet Hinoul dated January 14,
21	information sent to your previously closed	21	2014, and I'm opening it to the page that I'd like
22	submission.	22	for you to be looking at. It's actually page 1244.
23	And then there's a number and the	23	MS. KABBASH: You know what?
24	number would be different for each of the various	24	THE WITNESS: Okay. Do you need
25	e-mails; correct?	25	this?
	Page 507		Page 509
1	A. Yes.	1	MR. FREESE: Yes, sir.
2	MR. FREESE: Is this D-10? Okay. Go	2	(Pause.)
2	MR. FREESE: Is this D-10? Okay. Go ahead. You're good.	2	(Pause.) MR. FREESE: Is this the page we're
2 3 4	MR. FREESE: Is this D-10? Okay. Go ahead. You're good. BY MR. GAGE:	2 3 4	(Pause.) MR. FREESE: Is this the page we're looking at?
2 3 4 5	MR. FREESE: Is this D-10? Okay. Go ahead. You're good. BY MR. GAGE: Q. Then on the first e-mail that's part	2 3 4 5	(Pause.) MR. FREESE: Is this the page we're looking at? MR. GAGE: Yeah.
2 3 4 5 6	MR. FREESE: Is this D-10? Okay. Go ahead. You're good. BY MR. GAGE: Q. Then on the first e-mail that's part of the collective Exhibit D-10, it says June 5,	2 3 4 5 6	(Pause.) MR. FREESE: Is this the page we're looking at? MR. GAGE: Yeah. MR. FREESE: Did you mark this
2 3 4 5 6 7	MR. FREESE: Is this D-10? Okay. Go ahead. You're good. BY MR. GAGE: Q. Then on the first e-mail that's part of the collective Exhibit D-10, it says June 5, 2015: Based solely on the information you have	2 3 4 5 6 7	(Pause.) MR. FREESE: Is this the page we're looking at? MR. GAGE: Yeah. MR. FREESE: Did you mark this already? It's P
2 3 4 5 6 7 8	MR. FREESE: Is this D-10? Okay. Go ahead. You're good. BY MR. GAGE: Q. Then on the first e-mail that's part of the collective Exhibit D-10, it says June 5, 2015: Based solely on the information you have provided, it does not appear that you have	2 3 4 5 6 7 8	(Pause.) MR. FREESE: Is this the page we're looking at? MR. GAGE: Yeah. MR. FREESE: Did you mark this already? It's P MR. GAGE: It's already marked.
2 3 4 5 6 7 8	MR. FREESE: Is this D-10? Okay. Go ahead. You're good. BY MR. GAGE: Q. Then on the first e-mail that's part of the collective Exhibit D-10, it says June 5, 2015: Based solely on the information you have provided, it does not appear that you have significantly changed or modified the design,	2 3 4 5 6 7 8 9	(Pause.) MR. FREESE: Is this the page we're looking at? MR. GAGE: Yeah. MR. FREESE: Did you mark this already? It's P MR. GAGE: It's already marked. THE WITNESS: 1638.
2 3 4 5 6 7 8 9	MR. FREESE: Is this D-10? Okay. Go ahead. You're good. BY MR. GAGE: Q. Then on the first e-mail that's part of the collective Exhibit D-10, it says June 5, 2015: Based solely on the information you have provided, it does not appear that you have significantly changed or modified the design, components, method of manufacture, or intended use	2 3 4 5 6 7 8 9	(Pause.) MR. FREESE: Is this the page we're looking at? MR. GAGE: Yeah. MR. FREESE: Did you mark this already? It's P MR. GAGE: It's already marked. THE WITNESS: 1638. MR. GAGE: P-1638.
2 3 4 5 6 7 8 9 10	MR. FREESE: Is this D-10? Okay. Go ahead. You're good. BY MR. GAGE: Q. Then on the first e-mail that's part of the collective Exhibit D-10, it says June 5, 2015: Based solely on the information you have provided, it does not appear that you have significantly changed or modified the design, components, method of manufacture, or intended use of the device. Additionally, we did not review any	2 3 4 5 6 7 8 9 10	(Pause.) MR. FREESE: Is this the page we're looking at? MR. GAGE: Yeah. MR. FREESE: Did you mark this already? It's P MR. GAGE: It's already marked. THE WITNESS: 1638. MR. GAGE: P-1638. BY MR. GAGE:
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55 (Pages 506 to 509)

	Page 510		Page 512
1	your recollection about. It was question: One of	1	excessive contraction occurs in a TVT device?
2	the known adverse events is clinically significant	2	MR. BARLOW: Object to form.
3	compression rephrase. One of the known adverse	3	THE WITNESS: Theoretically, yes.
4	events is what is termed as contraction of the mesh;	4	BY MR. GAGE:
5	correct? Answer: I disagree with that.	5	Q. What was the evidence, if any, that
6	Question: Because I called it	6	the company had to demonstrate that excessive
7	contraction of the mesh. Answer: Correct.	7	contraction was, in fact, occurring in TVT devices?
8	Question: One of the known adverse events is	8	MR. FREESE: Object to the form of
9	contraction; correct? Answer: Contraction of the	9	the question.
10	tissue around the mesh, yes.	10	THE WITNESS: Well, I don't know that
11	Question: And we're talking in this	11	we had any evidence that it was that excessive
12	context of the scar tissue forming around the mesh	12	contraction was occurring.
13 14	that compresses down and contracts the mesh;	13 14	BY MR. GAGE:
15	correct? Answer: Squeeze the mesh so it's	15	Q. Now, can you explain to the jury whether mesh contracts and when I say mesh, I'm
16	enveloped in the scar and that is retracted, yes. So the total mesh scar, that is what contracts.	16	talking about the mesh in well, strike that.
17	I think I've heard that referred to	17	Can you describe for the jury
18	as the scar mesh complex. Answer: That's an	18	strike that.
19	appropriate way of putting it.	19	Does mesh contract?
20	Did I read that correctly?	20	MR. FREESE: Object to form
21	A. Yes.	21	MR. GAGE: After it's implanted in
22	Q. Now, you were asked some questions	22	the body?
23	about that testimony. Anywhere in this section, is	23	MR. FREESE: Object to the form of
24	there any reference to excessive contraction?	24	the question.
25	MR. FREESE: Object to the form of	25	THE WITNESS: The mesh itself does
	Page 511		Page 513
1		1	Page 513 not contract. The fibers of the mesh do not
1 2	Page 511 the question. THE WITNESS: The word "excessive" is	1 2	
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Page 516 Page 514 1 THE WITNESS: Well, what happens to 1 grows into the scaffold and then supports the 2 2 the mesh when it's implanted is that the tissue from urethra. So a little bit of contraction is good in 3 3 the body -- the body tissues grow into those little that case. 4 holes and really wind up encapsulating the mesh in 4 And we know it happens and that's why 5 tissue in and out of the holes and all around it. 5 we make it loose when we put it in, so that we don't 6 6 So if that tissue contracts, it pulls the mesh with get obstruction. 7 7 MR. BARLOW: Object as nonresponsive. 8 8 The mesh itself, the fibers of the BY MR. GAGE: 9 mesh, don't contract, but the complex of the scar 9 All right. O. 10 tissue -- and that's what -- that's what it is. 10 Yesterday, during your deposition, 11 It's a -- it's supposed to be a scarring type of 11 you were asked a question and I'm reading from the ingrowth; as that contracts, it takes the mesh with transcript. It said, question: Excessive 12 12 13 it, to some extent. 13 contraction or shrinkage of the tissue surrounding 14 BY MR. GAGE: 14 the mesh, as we've just discussed it, is that an adverse reaction with the TVT? Correct? Answer: 15 O. Is that contraction a good thing or a 15 Excessive, yes. 16 bad thing? 16 17 MR. FREESE: Object to the form of 17 And it would be reasonable and 18 the question. 18 feasible to include that in the IFU, particularly the adverse reactions section for the TVT; correct? 19 THE WITNESS: Well, it's a broad 19 20 20 Answer: It would be reasonable to include it. question. Are you referring to TVT? Question: And it would have been reasonable and 21 MR. GAGE: Yes. 21 22 THE WITNESS: In TVT, it's not 22 feasible to do so right from the beginning when the necessarily a bad thing. In fact, what it does, it 23 TVT first went on the market and the first IFU came 23 helps support the urethra. Now, that's going to out; correct? The witness: It would have been 24 24 25 require some explanation. 25 reasonable, yes, and feasible. Page 517 Page 515 1 The TVT works as a loop (Indicating) 1 Do you wish to clarify that 2 under the urethra --2 testimony? 3 MR. FREESE: Hold on one second, 3 MR. FREESE: Object to the form of Doctor. I object to the form of the question 4 4 the question. 5 5 because he asked you a question and you asked again, THE WITNESS: Well --6 so, I'm sorry, I object to the form of the question 6 MR. GAGE: Let me ask you this: Are 7 that Dr. Weisberg's answering right now. 7 those answers correct? 8 8 Go ahead. MR. FREESE: Object to the form of 9 9 THE WITNESS: Okay. So one of the the question. 10 problems with incontinence is that the urethra 10 THE WITNESS: They won't be correct drops, and the purpose of the sling is to go under 11 unless I can explain them. 11 the urethra and then up out of the way and anchor 12 12 MR. GAGE: Please explain. 13 itself into some kind of tissue. 13 MR. FREESE: Object to the form of 14 And as the tissue grows into this, it 14 the question. 15 helps support this mesh that we put in and kind of 15 THE WITNESS: And the fact is that 16 anchors or glues it; and as it contracts, it can --16 since we have no good cause-and-effect evidence that 17 it contracts a little bit. It doesn't contract a 17 this is an adverse reaction, at this point, I don't 18 18 whole lot, because if it did, it would block the think that it would be good to include it. 19 19 urine from coming out and we know that it doesn't do BY MR. GAGE: 20 that at the time that the mesh is working its way 20 Who made that decision when the --21 into the tissue. 21 when the company was looking at the changes 22 22 requested by Health Canada? So what happens is, the -- it essentially makes, like, new ligaments to hold up 23 I did. 23 A. 24 the urethra. So the mesh is a -- is a -- I'm 24 O. Sir, you were asked a question blanking on the word -- like a scaffold. The tissue 25 yesterday at your deposition -- and I'll read the 25

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Page 520 Page 518 1 question and answer to you. 1 becomes very clear that these cells are not going to 2 2 Do I have it here? be able to eat this; and in the process of trying to 3 3 MS. KABBASH: Actually, you know get rid of it, that's an acute foreign body 4 4 what? I don't think he does -reaction. 5 5 MR. GAGE: No, you don't. After a while, when it's clear that 6 6 I don't think I have to mark this as it's not going to work, the body in its wisdom sets 7 7 an exhibit because this is just a rough transcript up kind of a neutral zone where the foreign body 8 8 from yesterday, so I'm not going to mark that as an reaction isn't working, the acute foreign body 9 exhibit. 9 reaction isn't working, but it still identifies the 10 But, Dr. Weisberg, I'm handing you a 10 fact that the cells of the body are different from 11 11 copy of the rough transcript from yesterday's the implant. 12 proceedings where you were deposed, and if you could 12 So at the junction, just at the 13 turn to page 183? 13 junction, of the implant and the tissue, a different 14 THE WITNESS: (Witness complies.) 14 kind of cell comes in and a pathologist or a micro 15 BY MR. GAGE: 15 -- not a microbiologist -- a histologist will look under a microscope and say that this is defined by a 16 And at the bottom, at line 18, do you 16 17 see where the question begins, this IFU --17 number of parameters as a chronic foreign body 18 18 reaction. And that stays for the life of the -- of 19 O. -- question: This IFU does not 19 the device. 20 20 distinguish between an acute or a chronic foreign However, a chronic foreign body 21 body response. It just says that the foreign body 21 reaction does not cause the same kind of body 22 response in total is transitory. That is 22 effects that an acute one does. So there might be technically incorrect. Right? Objection. The 23 some inflammation in the beginning when these cells 23 24 witness: Hang on. Let me look at this. No, it 24 come in, but eventually, these cells and the foreign 25 doesn't say that. It says transitory local 25 body coexist. Page 519 Page 521 1 irritation and -- oh, yes, and a transitory foreign 1 And if -- if you understand what a 2 body response may occur. It says it's transitory. 2 chronic foreign body reaction is, it's not an 3 Yes. Question: That's technically incorrect 3 inflammatory condition. There are cells that 4 4 because it's chronic; correct? Objection. The identify it as a foreign body reaction, but, I mean, 5 5 witness: Yes. the way I learned it and the way it's always been is 6 Do you see that? 6 that if you're still having inflammation after two, 7 7 three weeks of the chronic foreign body reaction, I do. A. 8 8 you gotta look for something else like an infection. Q. Is that a correct answer? 9 9 MR. FREESE: Object to the form of The chronic foreign body reaction is 10 the question. 10 just there. You can see it on the microscope. The THE WITNESS: It's really not because 11 tissue is now working its way into -- into or around 11 12 I didn't get a chance to explain it. 12 this foreign body. It's walling it off -- it can't 13 MR. GAGE: Can you explain why your 13 get rid of it, so it's just walling it off -- and 14 prior answer is really not correct? 14 those cells where the tissue meets the foreign body, 15 THE WITNESS: Yes. It's not a yes or 15 that's called a chronic foreign body reaction. 16 no question. It requires explanation. It's going 16 So it was very difficult to answer to take me about two minutes to explain what foreign 17 that question with a yes or a no. 17 18 body reaction is and how it works in the body. 18 MR. FREESE: Move to strike: 19 When anything is implanted, anything, 19 nonresponsive. 20 the body tries to get rid of it; and one of the 20 BY MR. GAGE: 21 things that it does, it sends in cells to try to eat 21 Sir, if you would, turn to page 49 of 22 22 it, try to destroy it. And some of those cells, your deposition -- I'm sorry. Turn to page 49 of depending on what those cells are, are classified 23 the transcript of yesterday's proceedings when you 23 24 under the microscope as a foreign body reaction. 24 were deposed. 25 25 With something like polypropylene, it (Witness complies.) Okay.

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Page 524 Page 522 1 Line 20, there's a question that 1 THE WITNESS: Because it was common 2 2 reads, question: The adverse reactions that are knowledge to anyone who does this kind of surgery or 3 3 uses mesh. We knew it. Our consultants knew it. listed in the IFU for each of the devices at issue 4 here are accurate. Right? Objection. The witness: 4 The people who reviewed our IFUs knew it, and 5 Yeah, accurate, but not all inclusive. 5 basically anybody who's had any medical training 6 6 Do you see that? knows it. 7 7 Correct. BY MR. GAGE: A. 8 8 O. What does -- what do you mean by not O. You were asked a number of times 9 9 yesterday and today whether it would have been all inclusive? 10 MR. FREESE: Object to the form of 10 reasonable to warn about certain adverse events at 11 the question. 11 the time the various devices were launched. Do you recall those questions? 12 THE WITNESS: Instructions for use 12 13 tells the doctor what the device is. It tells him 13 A. I do. 14 when to use it, when not to use it, and lists some 14 O. Your answers were yes to most of 15 adverse reactions. 15 those. Do you recall that? 16 Any adverse reactions that are 16 Yes. A. specific to that device should absolutely be listed; 17 17 Q. Was it necessary to include those 18 but when you realize that most of the adverse 18 words in order for the IFUs to be adequate? 19 reactions are associated with any kind of surgery 19 MR. FREESE: Object to the form of 20 20 for this -- for this problem, you can't possibly -the question. 21 you don't need to possibly list everything that can 21 THE WITNESS: No. 22 go wrong in surgery. 22 BY MR. GAGE: 23 23 It's common knowledge. People Why not? 24 understand what can happen in surgery. People 24 MR. FREESE: Same objection. 25 understand that surgery hurts. People understand 25 THE WITNESS: As I mentioned before, Page 525 1 that surgery sometimes needs to be redone. People 1 some of those things -- most of those things --2 understand that surgery doesn't always work. 2 refer to the general adverse events associated with 3 And for those reasons and for -- with 3 surgery and/or mesh implantation. the line that people who are doing this operation 4 BY MR. GAGE: 4 5 5 need to understand the treatment of stress Sir, you were asked a number of 6 incontinence and need to understand how to use this 6 questions about the various IFUs and whether they 7 7 warned of urge incontinence. Do you recall that? device, most of those things are really superfluous 8 8 and wouldn't affect the safety or effectiveness of A. 9 9 the device. Q. And in some instances, the phrase 10 BY MR. GAGE: 10 urge incontinence was not found in the IFUs. Do you When you reference people, are you 11 recall that? 11 0. 12 referring to doctors? 12 A. That's correct. 13 The surgeons who are using the 13 A. O. What is detrusor instability? 14 14 It's the medical term for urge device. A. 15 Now, Dr. Weisberg, you were asked a 15 incontinence. It also includes frequency. 0. 16 number of questions yesterday and today as to 16 Does the term detrusor instability whether Ethicon was aware of various risks at the 17 appear in the IFUs for the TVT family of products? 17 time the device first went on the market. 18 18 A. 19 19 Do you recall those questions? So were your answers correct when you 20 20 said the IFUs did not warn of urge incontinence? A. Yes. 21 How is it that Ethicon would know 21 MR. FREESE: Object to the form of 22 22 what the risks are of the device before the device the question. 23 even goes on the market? 23 THE WITNESS: They were not correct. 24 24 MR. FREESE: Object to the form of BY MR. GAGE: 25 25 Q. Dr. Weisberg, you've answered a the question.

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Page 526 Page 528 number of questions over the past two days by saying I'm paid by the hour, but limited to 2 2 histologically, yes or histologically, that is a number of hours. 3 3 correct. And all the time for your preparation 4 4 What do you mean by that? and giving the deposition is being compensated by 5 5 Well, I'll refer back to my previous Ethicon. A. 6 6 answer about chronic foreign body reaction, which A. I -- as I said, I haven't even worked 7 7 means, under the microscope, you see cells that that out. It has to be within a certain number of 8 8 hours. I don't know whether we can stretch that out define chronic foreign body reaction. 9 But chronic foreign body reaction is 9 over months or it'll be a -- I don't know. I 10 not something that causes inflammation after its 10 haven't worked it out yet. initial -- after the initial cells get in and the 11 11 What is the limit of the number of hours that you are allowed to work under the 12 coating starts on the foreign body. 12 13 MR. FREESE: Move to strike: 13 contract? 14 14 40 per month, but I don't know nonresponsive. A. 15 MR. GAGE: Dr. Weisberg, that's all I 15 whether that means 80 for two months or 80 -- you 16 16 know, or 40 a month, period. have now. 17 17 I understand. That's -- that's as MR. FREESE: Let's flip-flop real 18 much detail as I need, thank you. 18 quick. 19 THE VIDEO TECHNICIAN: The time is 19 Do you have a judgment how many hours 20 20 3:18. We're going off the record. you've spent in preparing for giving your deposition 21 (A recess was taken from 3:18 p.m. to 21 over the last couple days? 22 3:26 p.m.) 22 Well, I can estimate. Wednesday, we A. THE VIDEO TECHNICIAN: The time is 23 23 spent about four hours. Last Thursday, we spent 24 3:26. We're back on the record. 24 maybe six or seven hours. Last Friday was about 25 25 five and a half hours, and I did some review at Page 527 Page 529 1 1 home. I didn't really -- I didn't really track 2 2 hours for that, but several -- several evenings of **EXAMINATION** 3 3 reviewing documents. 4 4 BY MR. FREESE: All right. O. 5 So the 20 or so hours that you're 5 Dr. Weisberg, you testified on 6 examination for Mr. Gage that you had retired in 6 saying you were preparing, not at home, you were 7 7 with the lawyers for Ethicon getting ready for your August of this year; is that correct? 8 8 A. Retired as a full-time employee. testimony; correct? 9 9 And you're now a consultant for Q. A. Yes. Ethicon? 10 10 Q. Was Maha preparing you? 11 11 A. Yes. A. Maha was there, yes. 12 12 Mr. Gage? Okay. Q. Q. 13 13 And are you being paid to be here Yes. A. 14 14 today? 0. Who else? 15 I assume so. 15 Mr. Gage wasn't there all the time. A. A. 16 Q. Okay. How much are you being paid to 16 Q. And -be here? 17 17 I spoke to -- we brought Stacy Kluesner in because I had a bunch of questions for I don't know. I'm limited to a 18 18 A. 19 number of hours that my contract limits me to, and I 19 her. I spoke to Piet Hinoul for a little bit. 20 don't know how they're going to work that out. 20 There was somebody else that came in and I don't 21 Okay. 2.1 remember who it was. Q. 22 22 You don't need to tell me the amount Were the lawyers always present when Q. of your contract, but whatever you're -- are you 23 23 you were speaking to Ms. Kluesner or Dr. Hinoul? 24 paid by the hour under your contract or is it a sum 24 No. I spoke to Dr. Hinoul on my own 25 some of the time, and they were present for one 25 certain?

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	Page 530		Page 532
1	phone call or two. I don't recall.	1	best of my knowledge.
2	Q. How many times did you speak to Dr.	2	BY MR. FREESE:
3	Hinoul?	3	Q. I understand, but you're here as a
4	A. I speak to him on a regular basis, so	4	fact witness on behalf of the company and not as an
5	I I can't parse out you know, I might have	5	expert witness; correct?
6	thrown a question here and there in other	6	A. That's what I
7	conversations.	7	MR. GAGE: Object to form.
8	Q. Did you speak to anybody not your	8	THE WITNESS: That's what I
9	lawyers last night?	9	understand.
10	A. No.	10	MR. FREESE: All right.
11	Q. That's a bad question. Did you speak	11	BY MR. FREESE:
12	to anyone other than your lawyers last night about	12	Q. Now, you listed for Mr. Gage I
13	this deposition or any of the questions you've been	13	think you said there were all kinds of RCTs
14	asked?	14	beginning in 1997 with the launch of TVT Retropubic.
15	A. I did.	15	Do you remember that?
16	Q. And who's that?	16	A. Yes.
17	A. I spoke to Piet.	17	Q. And you said there were a
18	Q. So after you gave your testimony	18	hundred-plus retropubic RCTs; correct?
19	yesterday, you went and called Dr. Hinoul?	19	A. Yes.
20	A. I did.	20	Q. And you said, starting 2004, there
21	Q. And there were no lawyers on the	21	were over 60 RCTs for TVT-O; correct?
22	phone?	22	A. Yes.
23	A. The lawyers were there.	23	Q. And you said there were over a
24	Q. Okay.	24	thousand case reports, including case reports, case
25	But you did speak to Dr. Hinoul with	25	series, and other kinds of scientific literature, on
	Page 531		Page 533
1	your lawyers on the phone last night after you gave	1	TVT and TVT-O; correct?
2	a deposition all day yesterday.	2	A. That's an estimate.
3	A. Yes.	3	Q. And that's all information in the
4	Q. And how long did that call last?	4	public domain, is it not?
5	A. Five minutes.	5	A. That's correct.
6	Q. Now, you are not hired by Ethicon to	6	Q. So it was as equally available to
7	be an expert witness in any of these cases, are you?	7	Marty Weisberg as it was Health Canada, was it not?
8	A. No.	8	A. Yes.
9	Q. You've not been designated as an	9	Q. So was there any data that was
10	expert?	10	available to you, scientific data that you were
11	A. Not no.	11	answering Mr. Gage's question, that was not also
12	Q. And you're not here giving any	12	available to Health Canada?
13	testimony as an expert witness; correct?	13	MR. GAGE: Object to form.
14	A. That's correct.	14	THE WITNESS: I don't think so.
15	Q. And to the extent that any Court	15	Everything was in public if not in the public
16	concludes that any opinion you've rendered is that	16	domain, was available for a price.
17	of which an expert would give, you would agree with	17	BY MR. FREESE:
18	me that Marty Weisberg's testimony should not be	18	Q. Everything you were testifying about
19	given as an expert witness.	19	you believe was in the public domain; correct?
20	MR. GAGE: Object to form.	20	A. Yes.
21	THE WITNESS: I think that's a legal	21	Q. And if it's in the public domain,
22	question that	22	it's equally available to Health Canada, isn't it?
23	MR. FREESE: It is.	23	A. Yes, it is.
24	THE WITNESS: the lawyers and the	24	Q. And your IFU was available to Health
25	Court have to determine. I I answered to the	25	Canada, was it not?

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Page 534
                                                                                                          Page 536
 1
         A.
                                                            1
                                                                     O.
                                                                           Does the FDA ever to your knowledge
 2
                                                            2
         Q.
               And despite their having access to
                                                                 -- strike that.
                                                            3
 3
     the thousands of case studies, the hundreds of TVT
                                                                          Since you've been working for
 4
     studies, the 60 TVT-O studies, they still demanded
                                                            4
                                                                 Ethicon, has the FDA ever instructed Ethicon not to
 5
     that you make all these changes to your IFUs for
                                                            5
                                                                 strengthen any of its warnings or precautions or
                                                            6
 6
     your TVT family of products, didn't it?
                                                                 adverse reactions of any of its products to your
 7
              MR. GAGE: Object to form.
                                                            7
                                                                 knowledge?
 8
                                                            8
              THE WITNESS: They requested that
                                                                     A.
                                                                           Not that I'm aware of.
 9
                                                            9
                                                                           So a hundred percent of your
     those changes be made, yes.
                                                                     Q.
10
              MR. FREESE: Even though they had
                                                            10
                                                                 experience, sir, is that if you're trying to
11
     access to all that same data you had; correct?
                                                           11
                                                                 strengthen a warning by changing the precautions,
              THE WITNESS: I don't know whether
                                                                 warnings, adverse events and provide more
12
                                                           12
13
     they accessed it or not, but they had access to it.
                                                           13
                                                                 information, more detailed information, the FDA has
14
     BY MR. FREESE:
                                                           14
                                                                 always endorsed that practice; correct?
15
               Absolutely. And despite having
                                                           15
                                                                          MR. GAGE: Object to form.
         O.
                                                                          THE WITNESS: I don't know all the
16
     access to it, Health Canada was not satisfied that
                                                           16
     your IFU was answering or providing the safety and
                                                           17
                                                                 circumstances when we tried to do this, but it's my
17
18
     efficacy information about the TVT family of
                                                           18
                                                                 understanding that they would not object.
19
     products in its minds; correct?
                                                           19
                                                                 BY MR. FREESE:
                                                           20
                                                                           Okay. So as you sit here today, you
20
              MR. GAGE: Object to form.
                                                                     O.
21
              THE WITNESS: I don't know what's in
                                                           21
                                                                 can't think of a single example when the FDA
22
     their minds, but they requested some changes.
                                                           22
                                                                 objected to you strengthening a warning.
                                                           23
23
     BY MR. FREESE:
                                                                          That's correct.
                                                           24
24
               You understand that they had access
                                                                          MR. GAGE: Object to form.
         O.
25
     to that scientific data, Health Canada was not
                                                           25
                                                                 BY MR. FREESE:
                                               Page 535
                                                                                                          Page 537
     satisfied that the IFUs that were used by Ethicon
 1
                                                            1
                                                                     Q.
                                                                           Now, you told us that you supplied
 2
     prior to May 29th of 2014 were adequate, was it?
                                                            2
                                                                 some data to Health Canada; correct?
 3
              MR. GAGE: Object to form.
                                                            3
                                                                     A.
                                                                           Yes.
              THE WITNESS: That's correct.
 4
                                                            4
                                                                           And you -- you will at least agree
                                                                     O.
                                                            5
 5
     BY MR. FREESE:
                                                                 with me that there is scientific data that's not so
 6
               They believed, in order to be full
                                                            6
                                                                 complimentary of the safety of TVT products;
 7
                                                            7
                                                                 correct? You'll give me that, won't you?
     and fair balanced, that you needed to make the
                                                            8
 8
     changes that your company went through to make;
                                                                           You mean generally not --
                                                                     A.
 9
                                                            9
     correct?
                                                                     Q.
                                                                           Yes, sir.
10
              MR. GAGE: Object to form.
                                                           10
                                                                     A.
                                                                           No, I think that the specifics of all
11
              THE WITNESS: That's what we
                                                           11
                                                                 the articles that talk about adverse events don't
12
                                                           12
                                                                 demonize the whole project -- the product.
     inferred.
                                                           13
                                                                           I withdraw the question. It was a
13
     BY MR. FREESE:
14
                                                           14
                                                                 bad question.
               Same question -- same question with
15
     respect to the FDA, Dr. Weisberg, and we're going to
                                                           15
                                                                          You will agree with me that there is
16
     talk a little more about this, but all the
                                                           16
                                                                 scientific data demonstrating that TVTs can suffer
                                                           17
                                                                 from complications in greater numbers versus
17
     information that you're saying was available, the
     scientific studies that you told Mr. Gage about,
18
                                                           18
                                                                 traditional surgeries.
                                                           19
19
     that was all available to the FDA, was it not?
                                                                          MR. GAGE: Object to form.
20
                                                           20
                                                                          THE WITNESS: There are some papers
         A.
               That's correct.
21
               All right.
                                                           21
                                                                 that say that.
         Q.
22
                                                            22
              And not one change did the -- that
                                                                 BY MR. FREESE:
23
     was made to the IFUs was objected to by the FDA;
                                                           23
                                                                           Did you or anyone on behalf of
24
     correct?
                                                           24
                                                                 Ethicon supply those to Health Canada?
                                                           25
25
                                                                           I can't speak for every article that
         A.
               That's correct.
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Page 538 Page 540 1 was supplied because we supplied a lot of them, but 1 articles that you would consider not complimentary we tried to supply a fair and balanced group of 2 2 of any of your products. 3 3 studies. A. You know --4 4 Well, that's my question and I won't MR. GAGE: Object to the form. 5 go through all these with you, but Mr. Gage has a 5 THE WITNESS: -- generally scientific collection -- did you give us as the exhibit we 6 6 literature isn't positive or negative. It includes 7 discussed earlier all the submission to Health 7 all the findings, the successes, the failures, the 8 8 Canada? adverse events, and that's how -- generally how good 9 A. Yes. 9 published scientific literature goes. 10 So whatever's in there is the -- is 10 Very infrequently do you see anything O. 11 the universe of information that Ethicon supplied to 11 that -- that is a whole negative article. There's Health Canada in making its judgment as to these always a balance in the article of what the findings 12 12 13 changes to the IFU; correct? 13 were. 14 À. Yes. 14 BY MR. FREESE: 15 O. So I can look at them and see whether 15 O. And --16 or not any negative studies were given to Health 16 A. And I think you'll find those. Canada; is that correct? 17 17 And I didn't mean to suggest 18 MR. GAGE: Object to form. I think 18 otherwise, Dr. Weisberg. I'm simply asking that 19 what we have marked is the TVT, not the Gynemesh PS 19 I'll find a fair and balanced collection of data 20 submission. Right? Because the Gynemesh PS 20 that you sent to Health Canada, the good, the bad, 21 submission would have gone to Health Canada, too, 21 and the ugly. 22 and we didn't mark that. 22 A. Yes. 23 23 MR. FREESE: Well, then, let me O. And that's what being fair and 24 24 balanced means. qualify the question. 25 MR. GAGE: Qualify the question --25 A. Yes. Page 539 Page 541 1 limit it to TVT and --1 O. Okay. 2 2 Now, I want to ask you, at the time MS. KABBASH: I think it was the 3 3 -- if you'll look at -- you don't have to -- you're whole thing. welcome to look at it, but -- P-1636. That's the 4 MR. GAGE: Is it? 4 5 5 MS. KABBASH: I think it's the whole Hackman, one-page Hackman memo? 6 6 A. thing. 7 7 MR. GAGE: Oh, well, I'm sorry. I Mr. Gage showed that to you? Q. 8 8 thought --Yeah, I don't think it's in here. 9 9 You can ask the question. If I can answer it MS. KABBASH: I want to look at it 10 just to be absolutely sure, but I'm pretty sure --10 without the reference, I will. If not, I'll wait BY MR. FREESE: 11 and find it. 11 12 Well, let me ask it this way: Is it 12 Here's my question: Mr. Gage walked you through that memo. Am I correct? 13 13 your belief as you sit here, Dr. Weisberg, that 14 everything that was submitted to Health Canada 14 A. Yes 15 regarding all the products at issue, the Gynemesh 15 Q. And this -- this is what kicked off 16 PS, the TVT family of products, was included in the 16 the project to modify the TVT family of products exhibit here? 17 IFUs; correct? 17 18 18 Yes. It wasn't a kickoff. It was part of A. A. 19 19 So we can look and see if there was the -- part of the regime that we go through or the 20 any negative scientific data supplied to Health 20 regimen that we go through to try to do an evaluation. 21 Canada; correct? 21 22 22 A. Well, you can look. Q. It says initial product risk And see whether or not it was 23 Q. 23 assessment --24 actually a fair and balanced submission to them to 24 A. Well, yes, that's the initial product 25 risk assessment. The risk assessment is one piece see if you had included negative articles or

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Page 544 Page 542 1 of everything else that we've done. 1 product liability lawsuits over synthetic mesh. 2 2 And at the time that Mr. Hackman He was not --3 3 wrote this e-mail in September of 2014, there were MR. GAGE: Object to form. 4 4 MS. KABBASH: Object to form. tens of thousands of product liability lawsuits pending against Ethicon and Johnson & Johnson at 5 THE WITNESS: He was not supervised 6 that time; correct? 6 by the lawyers. 7 7 A. That's correct. BY MR. FREESE: 8 8 MR. GAGE: Object to form. O. The lawyers were on the team --9 BY MR. FREESE: 9 A. They were on the team. 10 So not only were you involved in this 10 MR. GAGE: Object to form. 11 team, but a bunch of lawyers who work for Ethicon 11 THE WITNESS: They were on the team. were also involved in this Health Canada response They may well have participated. They may well also 12 12 have waited for him to come up with that and see how 13 team, were they not? 13 14 14 it fit in with the rest of the project. A. Yes. 15 MR. GAGE: Object to form. 15 BY MR. FREESE: 16 BY MR. FREESE: 16 And, for example, when Mr. Hackman 17 17 writes in here that a review of the risk assessment In fact, not only lawyers for 18 Ethicon, but lawyers who actively manage the tens of 18 summaries -- and I'll paraphrase that. It's down at 19 thousands of product liability lawsuits were 19 the bottom -- that the IFU changes introduce no new 20 20 involved in the Health Canada response, were they design or user-related risk, nor increase any risk 21 not? 21 levels -- that was reviewed by the team before it 22 A. 22 was sent out, was it not? Yes. 23 23 MR. GAGE: Object to form. That may not have been reviewed by the team before it was sent out because I don't --24 BY MR. FREESE: 24 25 And those same lawyers were reviewing 25 who was it sent to? Page 545 1 memos like Mr. Hackman's in September of 2014 before 1 Q. It was sent to project file. 2 they got issued; correct? 2 Okay. I -- I don't know whether that A. 3 MR. GAGE: Object to form. 3 was -- once again, I'm going to try to explain this. THE WITNESS: I can't testify that 4 4 There are a lot of pieces that go 5 5 they have reviewed that. It was certainly into a project like this. Somebody may have said to 6 available. I don't know if it was sent to everyone 6 Mr. Hackman, review the risk -- the -- you know, the 7 on the team. I don't -- I -- you'd really need to 7 risk assessment documents and make sure that 8 8 check with the lawyers for that. everything was what he said it was. 9 9 BY MR. FREESE: They may have taken that and may not 10 Well, you had no problem telling Mr. 10 have reviewed those risk documents themselves, but 11 Gage that this document was created in the normal 11 they certainly saw that letter at some point, yes. 12 course of business, that Mr. Hackman had personal 12 The lawyers for Ethicon were looking 13 knowledge of what he was doing at the time he was 13 -- if they were on the team, they were looking at 14 doing it -- you didn't write this memo; correct? project file documents, were they not? That's part 14 15 A. That's correct. 15 of what they were looking at. 16 But you had no problem telling Mr. 16 A. Q. Yes. 17 Gage that Mr. Hackman knew all this himself, did 17 MR. GAGE: Object to form. you? You told us that, didn't you? 18 THE WITNESS: I just don't know 18 Well, he knew all of it, but he might whether they looked at it before he wrote it or 19 19 20 not have known it all before he wrote that memo. 20 after he wrote. 21 Q. I understand. 2.1 BY MR. FREESE: 22 22 And you don't even know whether or Yeah. A. 23 23 not they wrote it themselves, do you? But Mr. Hackman was doing this under 24 the supervision of the lawyers for Ethicon that were 24 MR. GAGE: Object to form. involved in defending these tens of thousands of 25 THE WITNESS: I know that Hackman was

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working on it. MR. FREESE: I understand that. THE WITNESS: And I MR. FREESE: I'm asking you a different question, sir. Do you know whether or not of Mr. Hackman's e-mail on project file was written in whole or in part by lawyers for Ethicony. MR. FREESE: Do you know that one way or the other? MR. GAGE: Object to form. THE WITNESS: I don't know that one way or the other. MR. FREESE: Object to form. THE WITNESS: Based on my knowledge, it could have been written by a lawyer; correct? MR. FREESE: Object to form. THE WITNESS: Based on my knowledge, it could have been written by a lawyer; correct? MR. FREESE: Object to form. THE WITNESS: Based on my knowledge, it could have been written by a lawyer; correct? MR. FREESE: Object to form. THE WITNESS: Based on my knowledge, it could have been written by a lawyer; correct? MR. FREESE: Object to form. THE WITNESS: Based on my knowledge, it could have been written by a lawyer; correct? MR. FREESE: Object to form. THE WITNESS: Based on my knowledge, it could have been written by a lawyer; correct? MR. FREESE: Object to form. THE WITNESS: Wall, we read both of them. We read the 2008 and we read the 2012. MR. FREESE: Well, we can look at that were in the 2008; correct? MR. FREESE: Well, we can look the same, they don't even look the same, the		Page 546		Page 548
2	1	working on it.	1	Q. This patient brochure, Defense
THE WITNESS: And 1— MR, FREESE: Im asking you a solfferent question, sir: Do you know whether or not my hold or in part by lawyers for Ethicon? MR, GAGE: Object to form. THE WITNESS: I don't know that one way or the other. MR, GAGE: Object to form. THE WITNESS: I don't know that one way or the other. MR, GAGE: Object to form. THE WITNESS: I don't know that one way or the other. MR, GAGE: Object to form. THE WITNESS: Based on your knowledge, it could have been written by a lawyer; correct? MR, GAGE: Object to form. THE WITNESS: Based on my knowledge, it could have been written by a lawyer; correct? MR, GAGE: Object to form. THE WITNESS: Based on my knowledge, it could have been written by a lawyer; correct? MR, FREESE: MR, GAGE: Object to form. THE WITNESS: Based on my knowledge, it could have been written by a lawyer; correct? MR, FREESE: Object to form. THE WITNESS: Based on my knowledge, it could have been written by a lawyer; correct? MR, FREESE: Object to form. THE WITNESS: Based on my knowledge, it could have been written by a lawyer; correct? MR, FREESE: Object to form. THE WITNESS: Based on my knowledge, it could have been written by a lawyer; correct? MR, FREESE: Object to form. THE WITNESS: Based on my knowledge, it could have been written by a lawyer; correct? MR, FREESE: Object to form. THE WITNESS: Based on my knowledge, it could have been written by a lawyer; correct? MR, FREESE: Object to form. THE WITNESS: With we read both of them. We read the 2008 and we read the 2012. MR, FREESE: Thas that written in the 2008; correct? MR, GAGE: Object to form. THE WITNESS: My understanding was that he wrote it. MR, GAGE: Object to form. THE WITNESS: With we read both of them. We read the 2008; correct? MR, FREESE: MR, GAGE: Object to form. THE WITNESS: With we read the 2012. MR, FREESE: With we can look at the the wrote it was the wrote it. MR, GAGE: Object to form. THE WITNESS: I don't even look the same. They have different pictures. Q. Did you ask him in preparation for this deposition whether he wrote	2		2	
MR. FREESE: I'm asking you a 5 6 different question, sir. Do you know whether or not 6 Mr. Hackman's e-mail on project file was written in 7 whole or in part by lawyers for Ethicon? 8 MR. GAGE: Object to form. 9 MR. FREESE: Do you know that one way 11 2 THE WITNESS: I don't know that one way 12 2 way or the other. 13 way or the other. 14 BY MR. FREESE: Q. Based on your knowledge, it could 15 have been written by a lawyer; correct? 16 was been written by a lawyer; correct? 17 MR. GAGE: Object to form. 18 MR. FREESE: Object to form. 19 MR. FREESE: Object to form. 19 MR. GAGE: Object to form. 19 MR. FREESE: O	3	THE WITNESS: And I	3	
6 Mr. Hackman's e-mail on project file was written in whole or in part by lawyers for Ethicon? 8 MR. GAGE: Object to form. 9 MR. FREESE: Do you know that one way or the other? 11 MR. GAGE: Object to form. 12 THE WITNESS: I don't know that one way or the other. 13 way or the other. 14 BY MR. FREESE: 15 Q. Based on your knowledge, it could have been written by a lawyer; correct? 16 have been written by a lawyer; correct? 17 MR. GAGE: Object to form. 18 MS. KABBASH: Object to form. 19 THE WITNESS: Based on my knowledge, it could have been written by a lawyer; correct? 10 Idon't know who wrote it. 11 MR. FREESE: Object to form. 12 BY MR. FREESE: Object to form. 13 MR. FREESE: Object to form. 14 BY MR. FREESE: Object to form. 15 MR. GAGE: Object to form. 16 MR. GAGE: Object to form. 17 MR. GAGE: Object to form. 18 MR. GAGE: Object to form. 19 MR. GAGE: Object to form. 10 MR. GAGE: Object to remember. 11 THE WITNESS: Well, we read both of the wrote it. 11 MR. FREESE: Well, we read both of the wrote it. 12 MR. FREESE: Well, we can look at that were in the 2008; correct? 14 Wrote it personally you don't have personal that were in the 2008; correct? 15 Q. Did you alk to him and ask him if he wrote? 16 A. No. 17 MR. GAGE: Object to remember. 18 MR. GAGE: Object to remember. 19 Q. Did you alk to him and ask him if he wrote? 20 A. No. 21 MR. FREESE: Wal, we read both of the wrote it. 22 MR. FREESE: Well, we can look at that. But I'm asking you, you don't know what was anded to this 2012 23 MR. FREESE: Well, we can look at the wrote it. 24 BY MR. FREESE: Well, we can look at that. But I'm asking you, you don't know what was in Defendant's A versus 25 MR. FREESE: 26 Q. Did you skim in preparation for this deposition whether he wrote this memo? 27 A. No. 28 MR. FREESE: Wal, we read both of the wrote it. 29 MR. FREESE: Well, we can look at the wrote it. 30 MR. FREESE: Well, we can look at the wrote it. 31 MR. FREESE: Well, we can look at the wrote it. 32 MR. FREESE: Well, we can look at the wrote it. 33 MR. FREESE: Well, w	4	MR. FREESE: I'm asking you a	4	
whole or in part by lawyers for Ethicon? 8 M.R. GAGE: Object to form. 9 M.R. GAGE: Object to form. 10 or the other? 11 M.R. GAGE: Object to form. 12 THE WITNESS: I don't know that one 12 or the other. 13 A. No. A. No. A. Well, we spoke many times. A. Well, we spoke many times. A. Well, we spoke many times. A. No. Did you sak him in preparation for the worder. A. Well, we spoke many times. A. No.	5	different question, sir: Do you know whether or not	5	edition.
whole or in part by lawyers for Ethicon? 8 M.R. GAGE: Object to form. 9 M.R. GAGE: Object to form. 10 or the other? 11 M.R. GAGE: Object to form. 12 THE WITNESS: I don't know that one 12 or the other. 13 A. No. A. No. A. Well, we spoke many times. A. Well, we spoke many times. A. Well, we spoke many times. A. No. Did you sak him in preparation for the worder. A. Well, we spoke many times. A. No.	6	Mr. Hackman's e-mail on project file was written in	6	Q. I understand.
MR. GAGE: Object to form. MR. GAGE: Object to form. MR. GAGE: Object to form. THE WITNESS: I don't know that one way or the other. MR. GAGE: Object to form. MR. FREESE: MR. FREESE: Okay. Idon't know who wrote it. MR. FREESE: Okay. MR. FREESE: Okay. MR. FREESE: Okay. MR. FREESE: Way. MR. GAGE: Object to form. THE WITNESS: The were things in the worde it. MR. GAGE: Object to remember. MR. GAGE: Object to form. THE WITNESS: Idon't recall off the top of my head. MR. FREESE: Way. MR. FREESE: MR. GAGE: Object to form. MR. FREESE: Way. MR. FREE	7		7	A. Yes.
or the other? MR. GAGE: Object to form. THE WITNESS: I don't know that one way or the other. MR. GAGE: Object to form. MR. KABBASH: Object to form. MR. KABBASH: Object to form. MR. FREESE: Object to remember. THE WITNESS: My understanding was that he wrote it. MR. FREESE: Object to remember. THE WITNESS: My understanding was that he wrote it. MR. FREESE: Object to remember. THE WITNESS: My understanding was that he wrote it. MR. FREESE: Object to remember. THE WITNESS: My understanding was that he wrote it. MR. GAGE: Object to remember. THE WITNESS: My understanding was that he wrote it. MR. FREESE: Object to remember. THE WITNESS: My understanding was that he wrote it. MR. FREESE: Object to remember. THE WITNESS: My understanding was that he wrote it. MR. FREESE: Object to remember. THE WITNESS: My understanding was that he wrote it. MR. FREESE: Object to remember. THE WITNESS: My understanding was that he wrote it. MR. FREESE: Object to form. MR. GAGE: Object to form. MR. FREESE: Q. Did you simply surmise that because MR. FREESE: Q. Did you simply surmise that because MR. FREESE: Q. Did you simply surmise that because MR. FREESE: Q. Did you simply surmise that because MR. FREESE: Q. Now, Mr. Gage showed you	8		8	Q. But
or the other? MR. GAGE: Object to form. THE WITNESS: I don't know that one way or the other. BY MR. FREESE: MR. GAGE: Object to form. THE WITNESS: I don't know that one way or the other. MR. GAGE: Object to form. THE WITNESS: Based on your knowledge, it could have been written by a lawyer; correct? MR. GAGE: Object to form. THE WITNESS: Based on my knowledge, it could have been written by a lawyer; correct? MR. GAGE: Object to form. THE WITNESS: Based on my knowledge, it could have been written by a lawyer; correct? MR. GAGE: Object to form. THE WITNESS: Based on my knowledge, it could have been written by a lawyer; correct? I don't know who wrote it. MR. FREESE: Okay. MR. FREESE: The talking about this one right here, sir, Defendant's Exhibit No. 4. THE WITNESS: Well, we read both of them. We read the 2008 and thing about this one right here, sir, Defendant's Exhibit No. 4. THE WITNESS: Well, we can look at that. But I'm asking you, you don't know what was been writed that were in the 2008; correct? MR. FREESE: Well, we can look at that. But I'm asking you, you don't know what was been writed by a lawyer was added to this 2012 MR. GAGE: Object to form. MS. KABBASH: Object to form. THE WITNESS: Well, we read both of the were in the 2008; correct? MR. FREESE: Well, we can look at that. But I'm asking you, you don't know what was been writed by a lawyer was a down and did a comparison whether he wrote this memo? MR. GAGE: Object to form. MR. GAGE: Object to form. MR. GAGE: Object to form. MR. FREESE: Q. Did you sak him in preparation for this dependent's brack was don't was and every and about what are the risks, you have no idea whether or not that was in a version prior to 2012, do you? MR. FREESE: Well, we read beto 00? MR. FREESE: Well, we can look at that. But I'm asking you, you don't know what was beer in the 2008; correct? Page 549 MR. GAGE: Object to form. MR. GAGE: Object to form. MR. FREESE: Q. Did you	9		9	A. That one was created 2012.
THE WITNESS: I don't know that one way or the other. Way or the other. Q. Based on your knowledge, it could have been written by a lawyer; correct? MR. GAGE: Object to form. THE WITNESS: Based on my knowledge, it could have been written by a lawyer; correct? MR. GAGE: Object to form. THE WITNESS: Based on my knowledge, it could have been written by a lawyer; correct? MR. GAGE: Object to form. THE WITNESS: Wall, we read both of them. We read the 2012. MR. FREESE: The talking about this one right here, sir, Defendant's Exhibit No. 4. THE WITNESS: There were things in there that were in the 2008; correct? MR. FREESE: Well, we can look at that. But I'm asking you, you don't know what was THE WITNESS: My understanding was that he wrote it. MR. GAGE: Object to remember. THE WITNESS: My understanding was that he wrote it. BY MR. FREESE: Q. Did you talk to him and ask him if he wrote? A. Well, we spoke many times. Q. Did you ask him in preparation for this deposition whether he wrote this memo? MR. GAGE: Object to form. MR. GAGE: Object to form. THE WITNESS: There were things in there that were in the 2008; correct? MR. FREESE: Well, we can look at that. But I'm asking you, you don't know what was THE WITNESS: There were things in there that were in the 2008; correct? MR. FREESE: Well, we can look at that. But I'm asking you, you don't know what was THE WITNESS: There were things in there that were in the 2008; correct? MR. FREESE: Well, we can look at that. But I'm asking you, you don't know what was THE WITNESS: There were things in there, sir, Defendant's Exhibit 4. 4. THE WITNESS: There were things in them. We read the 2008 about this one right here, sir, Defendant's Exhibit 4. 6. THE WITNESS: There were things in them. We read the 2008; correct? MR. FREESE: Well, we cad both of them. We read the 2008 about this anneal them. We read the 2008 about this one right here, sir, Defendant's Exhibit 4. THE WITNESS: There were things in them. We read the 2008 about this one right here, sir, De	10		10	Q. So you and Mr. Gage didn't go through
13	11	MR. GAGE: Object to form.	11	the discussion of what was added to this 2012
14 BY MR. FREESE: Q. Based on your knowledge, it could have been written by a lawyer; correct? MR. GAGE: Object to form. MR. GAGE: Object to form. THE WITNESS: Based on my knowledge, 1 don't know who wrote it. MR. FREESE: Q. So you don't know if Mr. Hackman wrowledge of that, do you? MR. GAGE: Object to form. THE WITNESS: Wall, we read both of them. We read the 2012. MR. FREESE: I'm talking about this one right here, sir, Defendant's Exhibit No. 4. THE WITNESS: There were things in the wrote it. MR. GAGE: Object to remember. THE WITNESS: Well, we can look at that. But I'm asking you, you don't know what was Page 549 MR. GAGE: Object to remember. THE WITNESS: Well, we can look at that. But I'm asking you, you don't know what was Page 549 MR. GAGE: Object to form. THE WITNESS: I don't recall loft he wrote? A. Well, we spoke many times. Q. Did you talk to him and ask him if he wrote? MR. GAGE: Object to remember. THE WITNESS: I don't recall off the top of my head. THE WITNESS: I don't recall off the top of my head. THE WITNESS: I don't recall off the top of my head. THE WITNESS: I don't recall off the top of my head. THE WITNESS: I don't recall off the top of my head. THE WITNESS: A. No. MR. GAGE: Object to form. THE WITNESS: Here were things in there that were in the 2008; correct? MR. FREESE: Well, we can look at that. But I'm asking you, you don't know what was Page 549 Page 547 Page 549 Page 549 Page 547 A. Well, we spoke many times. Q. Did you ask him in preparation for this deposition whether he wrote this memo? A. No. MR. GAGE: Object to form. THE WITNESS: Well, we read both of them. We read the 2008 and we read the 2012. MR. FREESE: Well, we can look at that. But I'm asking you, you don't know what was Page 549 Page 549 Page 549 Page 549 Page 549 Page 549 A. No. Using now head. Q. Poid you ask him in preparation for this deposition whether he wrote this memo? A. No. Q. Did you ask him in preparation for this deposition whether he wrote this memo? A. No. Q. Did you si	12	THE WITNESS: I don't know that one	12	edition from the older edition, did you?
15		way or the other.	13	A. No.
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1	didn't get a patient brochure, they can't have the	1	the 2015, made no material changes in the safety or
2	benefit of it. Do you agree with that?	2	health risks regarding the use of the TVT products;
3	MR. GAGE: Object to form.	3	correct?
4	THE WITNESS: Well, I believe it was	4	MR. GAGE: Object to form.
5	on the Internet, also.	5	THE WITNESS: The
6	MR. FREESE: Sir, I'm listen to my	6	MR. FREESE: Or is it not? I'm
7	question.	7	paraphrasing your testimony. Is or is that not what
8	BY MR. FREESE:	8	your testimony is?
9	Q. If the patient brochure is not given	9	MR. GAGE: Object to form.
10	to the doctor and the doctor's not looking for your	10	THE WITNESS: It made no difference
11	patient brochure on the Internet, not going to have	11	in the health risks, no.
12 13	that information that's contained in the hard copy;	12 13	BY MR. FREESE:
$\frac{13}{14}$	correct? A. That's correct.	14	Q. In your view, it made no difference
15	Q. And you're not suggesting that any	15	in the health risk. It didn't supply the doctor with any information they didn't already know;
16	particular doctor got either Defendant's Exhibit No.	16	correct?
17	3 or Exhibit No. 4; is that correct?	17	A. Yes.
18	A. I know that they were distributed. I	18	Q. In your view, it simply parroted, but
19	don't know to whom or to how many.	19	maybe in different language, the same warnings that
20	Q. And there's no record in Ethicon to	20	were already in the prior IFUs; correct?
21	say which doctor got which patient brochure or ever	21	MR. GAGE: Object to form.
22	got a patient brochure; correct?	22	THE WITNESS: That's another thing it
23	MR. GAGE: Object to form; beyond the	23	did.
24	scope.	24	BY MR. FREESE:
25	THE WITNESS: If there is, I'm not	25	Q. And I guess you can agree with me,
	Page 551		Page 553
1	Page 551 aware of it.	1	
1 2		1 2	Page 553 from a medical standpoint, Martin Weisberg thought this was a totally unnecessary task from the
	aware of it. MR. FREESE: Okay. Thank you. BY MR. FREESE:		from a medical standpoint, Martin Weisberg thought
2	aware of it. MR. FREESE: Okay. Thank you. BY MR. FREESE: Q. Now, I think you testified yesterday	2	from a medical standpoint, Martin Weisberg thought this was a totally unnecessary task from the
2 3 4 5	aware of it. MR. FREESE: Okay. Thank you. BY MR. FREESE: Q. Now, I think you testified yesterday and I think confirmed today and I'm looking at	2	from a medical standpoint, Martin Weisberg thought this was a totally unnecessary task from the standpoint of providing information to doctors about the safety and efficacy of your company's products. A. Yes.
2 3 4 5 6	aware of it. MR. FREESE: Okay. Thank you. BY MR. FREESE: Q. Now, I think you testified yesterday and I think confirmed today and I'm looking at Defense Exhibit No. 5 this was the I guess the	2 3 4 5 6	from a medical standpoint, Martin Weisberg thought this was a totally unnecessary task from the standpoint of providing information to doctors about the safety and efficacy of your company's products. A. Yes. Q. Yet, once you embarked on complying
2 3 4 5 6 7	aware of it. MR. FREESE: Okay. Thank you. BY MR. FREESE: Q. Now, I think you testified yesterday and I think confirmed today and I'm looking at Defense Exhibit No. 5 this was the I guess the voice mail it started with the voice mail back	2 3 4 5 6 7	from a medical standpoint, Martin Weisberg thought this was a totally unnecessary task from the standpoint of providing information to doctors about the safety and efficacy of your company's products. A. Yes. Q. Yet, once you embarked on complying with Health Canada on a project that you personally
2 3 4 5 6 7 8	aware of it. MR. FREESE: Okay. Thank you. BY MR. FREESE: Q. Now, I think you testified yesterday and I think confirmed today and I'm looking at Defense Exhibit No. 5 this was the I guess the voice mail it started with the voice mail back and forth with the FDA.	2 3 4 5 6 7 8	from a medical standpoint, Martin Weisberg thought this was a totally unnecessary task from the standpoint of providing information to doctors about the safety and efficacy of your company's products. A. Yes. Q. Yet, once you embarked on complying with Health Canada on a project that you personally believed was totally unnecessary, your group,
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2 3 4 5 6 7 8 9 10 11	aware of it. MR. FREESE: Okay. Thank you. BY MR. FREESE: Q. Now, I think you testified yesterday and I think confirmed today and I'm looking at Defense Exhibit No. 5 this was the I guess the voice mail it started with the voice mail back and forth with the FDA. Do you remember that exhibit? A. Yes. Q. You told Mr. Gage	2 3 4 5 6 7 8 9 10	from a medical standpoint, Martin Weisberg thought this was a totally unnecessary task from the standpoint of providing information to doctors about the safety and efficacy of your company's products. A. Yes. Q. Yet, once you embarked on complying with Health Canada on a project that you personally believed was totally unnecessary, your group, including all the lawyers for the company that were on the group, decided, we're going to put this change worldwide in every country in which we do
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	aware of it. MR. FREESE: Okay. Thank you. BY MR. FREESE: Q. Now, I think you testified yesterday and I think confirmed today and I'm looking at Defense Exhibit No. 5 this was the I guess the voice mail it started with the voice mail back and forth with the FDA. Do you remember that exhibit? A. Yes. Q. You told Mr. Gage A. I have it. Q. That's really kind of a reference point. You don't necessarily need it, but you're welcome to look at it. You told Mr. Gage that after Health Canada came in and required that these changes be made to your IFUs, Johnson & Johnson and Ethicon decided that you were going to go worldwide with these changes; is that correct? MR. GAGE: Object to form. THE WITNESS: That's correct. BY MR. FREESE:	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	from a medical standpoint, Martin Weisberg thought this was a totally unnecessary task from the standpoint of providing information to doctors about the safety and efficacy of your company's products. A. Yes. Q. Yet, once you embarked on complying with Health Canada on a project that you personally believed was totally unnecessary, your group, including all the lawyers for the company that were on the group, decided, we're going to put this change worldwide in every country in which we do business and sell our products; correct? MR. GAGE: Object to form. THE WITNESS: Correct. BY MR. FREESE: Q. Your IFUs are, the last time I counted, translated by 25 different languages. Does that sound about right? A. I don't know the exact number. Q. Sound about right? A. It's probably right. Q. In how many countries does Ethicon sell TVT and Gynemesh?

66 (Pages 550 to 553)

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Page 554
                                                                                                         Page 556
1
         A.
               I don't know.
                                                           1
                                                                         THE WITNESS: I don't recall that
2
         Q.
                                                           2
               On six continents?
                                                               throughout the discussions. I think everybody
3
                                                           3
                                                               agreed that what we added was good. Was it
         A.
               I suspect.
4
                                                           4
               I'm going to assume you don't sell in
                                                               necessary? Probably not.
5
     Antarctica, but anywhere where people permanently
                                                           5
                                                               BY MR. FREESE:
6
     live on this planet, these products are sold, are
                                                           6
                                                                    O.
                                                                          All right.
7
                                                           7
     they not?
                                                                         And so -- and that is my question:
8
                                                           8
         A.
               Well, it's the most widely used
                                                               As you sit here today, Dr. Weisberg, it's your
9
     product for this procedure.
                                                           9
                                                               recollection that the -- that the consensus of the
10
               And in 2015, over a totally
                                                           10
                                                               Health Canada response team was that this was a
11
     unnecessary change, in your view, the company
                                                          11
                                                               unnecessary exercise that you were going through.
     decided to change the IFU in every country in which
                                                                         MR. GAGE: Objection to the form.
12
                                                          12
13
     you do business; correct?
                                                          13
                                                                         THE WITNESS: It was necessary in
14
                                                          14
                                                               that it's a regulatory body and they asked for it.
         A.
             Yes.
15
              MR. GAGE: Object to form.
                                                          15
                                                                         MR. FREESE: And I apologize. That
16
     BY MR. FREESE:
                                                          16
                                                               was a bad question.
                                                          17
                                                               BY MR. FREESE:
17
         Q. For every product you sold; correct?
18
              MR. GAGE: Object to form.
                                                          18
                                                                          It was the consensus of your Health
19
              THE WITNESS: Yes.
                                                          19
                                                               Canada response team that from a medical safety
                                                          20
20
                                                               standpoint, this was an unnecessary exercise that
     BY MR. FREESE:
21
                                                          21
                                                               Health Canada was requiring you to go through.
         Ο.
             In every language in which it was
22
     sold under; correct?
                                                          22
                                                                         MR. GAGE: Object to form.
                                                          23
23
                                                                         THE WITNESS: Yes.
         A. Yes.
24
              MR. GAGE: Object to form.
                                                          24
                                                               BY MR. FREESE:
25
     BY MR. FREESE:
                                                          25
                                                                    Q. And you then took that unnecessary
                                              Page 555
                                                                                                         Page 557
1
               So the company translated these IFUs
                                                           1
                                                               work and translated it into every country, in every
2
     into 25 or more different languages to give
                                                           2
                                                                product, in every language in which your products
3
     information that Martin Weisberg believed was
                                                           3
                                                               are sold; correct?
                                                           4
4
     totally unnecessary.
                                                                    A.
                                                                          Yes.
                                                           5
5
               Totally unnecessary? I think they're
                                                                         MR. GAGE: Object to form.
6
     unnecessary, but I think there was no bad
                                                           6
                                                               BY MR. FREESE:
7
                                                           7
     information in there. And why not?
                                                                          And, Dr. Weisberg, I -- you were
                                                           8
8
               Did --
                                                               handed Defense Exhibit No. 6, which was the
         Q.
9
                                                           9
                                                               collection of all the redline versions that went to
         A.
               We had been -- we had been making an
10
     effort to harmonize our IFUs; and if one regulatory
                                                          10
                                                               the FDA.
     body says we need to put something in and there's
                                                          11
11
                                                                         Do you recall that?
12
     nothing wrong with that information, why not include
                                                          12
                                                                          Yes.
                                                                    A.
13
                                                          13
                                                                    O.
                                                                          And Mr. Gage asked you some questions
14
             MR. FREESE: Move to strike as
                                                          14
                                                                about communications between Ethicon and the FDA.
15
    nonresponsive.
                                                          15
                                                                You remember those questions?
16
                                                          16
     BY MR. FREESE:
                                                                    A.
                                                                          Yes.
                                                          17
17
               My question to you, Dr. Weisberg, is,
                                                                    Q.
                                                                          And he said that the FDA never
     did anyone on your team say, you know what, Health
                                                          18
                                                               ordered you to do this; is that correct?
18
19
     Canada's right, we do need to strengthen our
                                                          19
                                                                    A.
                                                                          That's correct.
20
     warnings, this is -- we do have some lapses here,
                                                          20
                                                                          And am I correct that no one in the
21
     we've got some gaps, this is a good plan and we need
                                                          21
                                                               FDA ever expressed to you or anyone else at Ethicon
                                                           22
22
     to strengthen and make our warnings clearer on
                                                               that it believed that this was an unnecessary
     safety? Did anybody on your team express such a
                                                          23
23
                                                               exercise?
24
     sentiment?
                                                          24
                                                                         That you weren't doing anything, you
                                                          25
                                                               weren't helping out, there's no -- there's no new
25
             MR. GAGE: Object to form.
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67 (Pages 554 to 557)

	Page 558		Page 560
1	information here, did anyone from the FDA ever say	1	Q. Who was present at the meeting when
2	that?	2	you requested Ms. Kluesner to provide you this
3	A. No.	3	document?
4	MR. GAGE: Object to form.	4	A. The attorneys sitting in the room
5	BY MR. FREESE:	5	now.
6	Q. What the FDA did was, once they were	6	Q. The two lawyers representing you now?
7	alerted that you were doing it, they wanted to see	7	A. Yes wait a minute. I that's a
8	it, they embraced it, and endorsed it; correct?	8	that's a good question. Was everybody together
9	A. Yes.	9	at that meeting? I don't know. But I know that
10	Q. All right.	10	there was a point at which we all four were in one
11	And I'm going to ask you a general	11	room vetting this.
12	question, Dr. Weisberg: All of these e-mails that	12	Q. So when you say we were all in a room
13	Mr. Gage showed you back and forth to the FDA and	13	vetting it, you, Ms. Kluesner, and the lawyers for
14	you told Mr. Gage that the person had personal	14	Ethicon were vetting your chronology.
15	knowledge and the e-mail was done at or about the	15	A. Yes.
16	time you remember all those questions?	16	Q. And you don't think that Ms. Kluesner
17	A. Yes.	17	supplied all these ETH.MESH. documents, do you?
18	Q. As you sit here today, you don't know	18	A. Oh, no. No, that was that was
19	which, if all, of those e-mails were either written	19	supplied by the attorneys.
20	by lawyers for Ethicon or reviewed by lawyers for	20	Q. Yeah. So if we look through all the
21	Ethicon before they were sent out.	21	pages 1 through 6 of your chronology, we know that
22	MR. GAGE: Object to form.	22	all the documents the document source, that is,
23	MR. FREESE: Correct?	23	what supports the event, and the date was supplied
24	THE WITNESS: I don't know. I know	24	by the lawyers for Ethicon; correct?
25	the phone call was not.	25	A. Right. I didn't request the document
	Page 559		Page 561
1	Page 559 BY MR. FREESE:	1	
1 2		1 2	sources. It was suggested that we put them in there
	BY MR. FREESE:		
2	BY MR. FREESE: Q. And all of these e-mails and	2	sources. It was suggested that we put them in there to make it easier for everybody to find the documents.
2	BY MR. FREESE: Q. And all of these e-mails and correspondence that Mr. Gage showed you was during	2 3	sources. It was suggested that we put them in there to make it easier for everybody to find the documents.
2 3 4	BY MR. FREESE: Q. And all of these e-mails and correspondence that Mr. Gage showed you was during 2014 and 2015; correct?	2 3 4	sources. It was suggested that we put them in there to make it easier for everybody to find the documents. Q. By the lawyers.
2 3 4 5	BY MR. FREESE: Q. And all of these e-mails and correspondence that Mr. Gage showed you was during 2014 and 2015; correct? A. Yes. Q. When you know and everyone at the company knows there are tens of thousands of product	2 3 4 5 6	sources. It was suggested that we put them in there to make it easier for everybody to find the documents. Q. By the lawyers. A. Yes.
2 3 4 5 6 7 8	BY MR. FREESE: Q. And all of these e-mails and correspondence that Mr. Gage showed you was during 2014 and 2015; correct? A. Yes. Q. When you know and everyone at the	2 3 4 5 6 7 8	sources. It was suggested that we put them in there to make it easier for everybody to find the documents. Q. By the lawyers. A. Yes. Q. Now, you remember Mr. Gage asked you
2 3 4 5 6 7 8	BY MR. FREESE: Q. And all of these e-mails and correspondence that Mr. Gage showed you was during 2014 and 2015; correct? A. Yes. Q. When you know and everyone at the company knows there are tens of thousands of product liability lawsuits pending against your company for these very products.	2 3 4 5 6 7 8	sources. It was suggested that we put them in there to make it easier for everybody to find the documents. Q. By the lawyers. A. Yes. Q. Now, you remember Mr. Gage asked you questions about your testimony yesterday Dr. Weisberg, do you have your rough transcript from yesterday?
2 3 4 5 6 7 8 9	BY MR. FREESE: Q. And all of these e-mails and correspondence that Mr. Gage showed you was during 2014 and 2015; correct? A. Yes. Q. When you know and everyone at the company knows there are tens of thousands of product liability lawsuits pending against your company for these very products. A. Yes.	2 3 4 5 6 7 8 9	sources. It was suggested that we put them in there to make it easier for everybody to find the documents. Q. By the lawyers. A. Yes. Q. Now, you remember Mr. Gage asked you questions about your testimony yesterday Dr. Weisberg, do you have your rough transcript from yesterday? A. Is that
2 3 4 5 6 7 8 9 10	BY MR. FREESE: Q. And all of these e-mails and correspondence that Mr. Gage showed you was during 2014 and 2015; correct? A. Yes. Q. When you know and everyone at the company knows there are tens of thousands of product liability lawsuits pending against your company for these very products. A. Yes. MR. GAGE: Object to form.	2 3 4 5 6 7 8 9 10	sources. It was suggested that we put them in there to make it easier for everybody to find the documents. Q. By the lawyers. A. Yes. Q. Now, you remember Mr. Gage asked you questions about your testimony yesterday Dr. Weisberg, do you have your rough transcript from yesterday? A. Is that Q. It's what Mr. Gage showed you.
2 3 4 5 6 7 8 9 10 11 12	BY MR. FREESE: Q. And all of these e-mails and correspondence that Mr. Gage showed you was during 2014 and 2015; correct? A. Yes. Q. When you know and everyone at the company knows there are tens of thousands of product liability lawsuits pending against your company for these very products. A. Yes. MR. GAGE: Object to form. BY MR. FREESE:	2 3 4 5 6 7 8 9 10 11 12	sources. It was suggested that we put them in there to make it easier for everybody to find the documents. Q. By the lawyers. A. Yes. Q. Now, you remember Mr. Gage asked you questions about your testimony yesterday Dr. Weisberg, do you have your rough transcript from yesterday? A. Is that Q. It's what Mr. Gage showed you. A this one?
2 3 4 5 6 7 8 9 10 11 12 13	BY MR. FREESE: Q. And all of these e-mails and correspondence that Mr. Gage showed you was during 2014 and 2015; correct? A. Yes. Q. When you know and everyone at the company knows there are tens of thousands of product liability lawsuits pending against your company for these very products. A. Yes. MR. GAGE: Object to form. BY MR. FREESE: Q. Now, Mr. Gage showed you D-9, this	2 3 4 5 6 7 8 9 10 11 12 13	sources. It was suggested that we put them in there to make it easier for everybody to find the documents. Q. By the lawyers. A. Yes. Q. Now, you remember Mr. Gage asked you questions about your testimony yesterday Dr. Weisberg, do you have your rough transcript from yesterday? A. Is that Q. It's what Mr. Gage showed you. A this one? MR. GAGE: Yeah, that's it.
2 3 4 5 6 7 8 9 10 11 12 13 14	BY MR. FREESE: Q. And all of these e-mails and correspondence that Mr. Gage showed you was during 2014 and 2015; correct? A. Yes. Q. When you know and everyone at the company knows there are tens of thousands of product liability lawsuits pending against your company for these very products. A. Yes. MR. GAGE: Object to form. BY MR. FREESE: Q. Now, Mr. Gage showed you D-9, this chronology of events?	2 3 4 5 6 7 8 9 10 11 12 13 14	sources. It was suggested that we put them in there to make it easier for everybody to find the documents. Q. By the lawyers. A. Yes. Q. Now, you remember Mr. Gage asked you questions about your testimony yesterday Dr. Weisberg, do you have your rough transcript from yesterday? A. Is that Q. It's what Mr. Gage showed you. A this one? MR. GAGE: Yeah, that's it. THE WITNESS: I have it.
2 3 4 5 6 7 8 9 10 11 12 13 14 15	BY MR. FREESE: Q. And all of these e-mails and correspondence that Mr. Gage showed you was during 2014 and 2015; correct? A. Yes. Q. When you know and everyone at the company knows there are tens of thousands of product liability lawsuits pending against your company for these very products. A. Yes. MR. GAGE: Object to form. BY MR. FREESE: Q. Now, Mr. Gage showed you D-9, this chronology of events? A. Yes.	2 3 4 5 6 7 8 9 10 11 12 13 14 15	sources. It was suggested that we put them in there to make it easier for everybody to find the documents. Q. By the lawyers. A. Yes. Q. Now, you remember Mr. Gage asked you questions about your testimony yesterday Dr. Weisberg, do you have your rough transcript from yesterday? A. Is that Q. It's what Mr. Gage showed you. A this one? MR. GAGE: Yeah, that's it. THE WITNESS: I have it. MR. FREESE: Can you identify the
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	BY MR. FREESE: Q. And all of these e-mails and correspondence that Mr. Gage showed you was during 2014 and 2015; correct? A. Yes. Q. When you know and everyone at the company knows there are tens of thousands of product liability lawsuits pending against your company for these very products. A. Yes. MR. GAGE: Object to form. BY MR. FREESE: Q. Now, Mr. Gage showed you D-9, this chronology of events? A. Yes. Q. Did any lawyer assist in the	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	sources. It was suggested that we put them in there to make it easier for everybody to find the documents. Q. By the lawyers. A. Yes. Q. Now, you remember Mr. Gage asked you questions about your testimony yesterday Dr. Weisberg, do you have your rough transcript from yesterday? A. Is that Q. It's what Mr. Gage showed you. A this one? MR. GAGE: Yeah, that's it. THE WITNESS: I have it. MR. FREESE: Can you identify the exhibit number? I don't have it
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	BY MR. FREESE: Q. And all of these e-mails and correspondence that Mr. Gage showed you was during 2014 and 2015; correct? A. Yes. Q. When you know and everyone at the company knows there are tens of thousands of product liability lawsuits pending against your company for these very products. A. Yes. MR. GAGE: Object to form. BY MR. FREESE: Q. Now, Mr. Gage showed you D-9, this chronology of events? A. Yes. Q. Did any lawyer assist in the preparation of Defense Exhibit No. 9?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	sources. It was suggested that we put them in there to make it easier for everybody to find the documents. Q. By the lawyers. A. Yes. Q. Now, you remember Mr. Gage asked you questions about your testimony yesterday Dr. Weisberg, do you have your rough transcript from yesterday? A. Is that Q. It's what Mr. Gage showed you. A this one? MR. GAGE: Yeah, that's it. THE WITNESS: I have it. MR. FREESE: Can you identify the exhibit number? I don't have it MR. GAGE: I didn't make it an
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	BY MR. FREESE: Q. And all of these e-mails and correspondence that Mr. Gage showed you was during 2014 and 2015; correct? A. Yes. Q. When you know and everyone at the company knows there are tens of thousands of product liability lawsuits pending against your company for these very products. A. Yes. MR. GAGE: Object to form. BY MR. FREESE: Q. Now, Mr. Gage showed you D-9, this chronology of events? A. Yes. Q. Did any lawyer assist in the preparation of Defense Exhibit No. 9? A. I requested it. I worked with Stacy	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	sources. It was suggested that we put them in there to make it easier for everybody to find the documents. Q. By the lawyers. A. Yes. Q. Now, you remember Mr. Gage asked you questions about your testimony yesterday Dr. Weisberg, do you have your rough transcript from yesterday? A. Is that Q. It's what Mr. Gage showed you. A this one? MR. GAGE: Yeah, that's it. THE WITNESS: I have it. MR. FREESE: Can you identify the exhibit number? I don't have it MR. GAGE: I didn't make it an exhibit number, but
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	BY MR. FREESE: Q. And all of these e-mails and correspondence that Mr. Gage showed you was during 2014 and 2015; correct? A. Yes. Q. When you know and everyone at the company knows there are tens of thousands of product liability lawsuits pending against your company for these very products. A. Yes. MR. GAGE: Object to form. BY MR. FREESE: Q. Now, Mr. Gage showed you D-9, this chronology of events? A. Yes. Q. Did any lawyer assist in the preparation of Defense Exhibit No. 9? A. I requested it. I worked with Stacy on it. I don't know if or what kind of input the	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	sources. It was suggested that we put them in there to make it easier for everybody to find the documents. Q. By the lawyers. A. Yes. Q. Now, you remember Mr. Gage asked you questions about your testimony yesterday Dr. Weisberg, do you have your rough transcript from yesterday? A. Is that Q. It's what Mr. Gage showed you. A this one? MR. GAGE: Yeah, that's it. THE WITNESS: I have it. MR. FREESE: Can you identify the exhibit number? I don't have it MR. GAGE: I didn't make it an exhibit number, but MR. FREESE: Okay. That's fair
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	BY MR. FREESE: Q. And all of these e-mails and correspondence that Mr. Gage showed you was during 2014 and 2015; correct? A. Yes. Q. When you know and everyone at the company knows there are tens of thousands of product liability lawsuits pending against your company for these very products. A. Yes. MR. GAGE: Object to form. BY MR. FREESE: Q. Now, Mr. Gage showed you D-9, this chronology of events? A. Yes. Q. Did any lawyer assist in the preparation of Defense Exhibit No. 9? A. I requested it. I worked with Stacy on it. I don't know if or what kind of input the attorneys had. I just got this after I requested	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	sources. It was suggested that we put them in there to make it easier for everybody to find the documents. Q. By the lawyers. A. Yes. Q. Now, you remember Mr. Gage asked you questions about your testimony yesterday Dr. Weisberg, do you have your rough transcript from yesterday? A. Is that Q. It's what Mr. Gage showed you. A this one? MR. GAGE: Yeah, that's it. THE WITNESS: I have it. MR. FREESE: Can you identify the exhibit number? I don't have it MR. GAGE: I didn't make it an exhibit number, but MR. FREESE: Okay. That's fair enough.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	BY MR. FREESE: Q. And all of these e-mails and correspondence that Mr. Gage showed you was during 2014 and 2015; correct? A. Yes. Q. When you know and everyone at the company knows there are tens of thousands of product liability lawsuits pending against your company for these very products. A. Yes. MR. GAGE: Object to form. BY MR. FREESE: Q. Now, Mr. Gage showed you D-9, this chronology of events? A. Yes. Q. Did any lawyer assist in the preparation of Defense Exhibit No. 9? A. I requested it. I worked with Stacy on it. I don't know if or what kind of input the attorneys had. I just got this after I requested it.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	sources. It was suggested that we put them in there to make it easier for everybody to find the documents. Q. By the lawyers. A. Yes. Q. Now, you remember Mr. Gage asked you questions about your testimony yesterday Dr. Weisberg, do you have your rough transcript from yesterday? A. Is that Q. It's what Mr. Gage showed you. A this one? MR. GAGE: Yeah, that's it. THE WITNESS: I have it. MR. FREESE: Can you identify the exhibit number? I don't have it MR. GAGE: I didn't make it an exhibit number, but MR. FREESE: Okay. That's fair enough. BY MR. FREESE:
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	BY MR. FREESE: Q. And all of these e-mails and correspondence that Mr. Gage showed you was during 2014 and 2015; correct? A. Yes. Q. When you know and everyone at the company knows there are tens of thousands of product liability lawsuits pending against your company for these very products. A. Yes. MR. GAGE: Object to form. BY MR. FREESE: Q. Now, Mr. Gage showed you D-9, this chronology of events? A. Yes. Q. Did any lawyer assist in the preparation of Defense Exhibit No. 9? A. I requested it. I worked with Stacy on it. I don't know if or what kind of input the attorneys had. I just got this after I requested it. Q. You requested this chronology from	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	sources. It was suggested that we put them in there to make it easier for everybody to find the documents. Q. By the lawyers. A. Yes. Q. Now, you remember Mr. Gage asked you questions about your testimony yesterday Dr. Weisberg, do you have your rough transcript from yesterday? A. Is that Q. It's what Mr. Gage showed you. A this one? MR. GAGE: Yeah, that's it. THE WITNESS: I have it. MR. FREESE: Can you identify the exhibit number? I don't have it MR. GAGE: I didn't make it an exhibit number, but MR. FREESE: Okay. That's fair enough. BY MR. FREESE: Q. If you'll turn to page 175, Dr.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	BY MR. FREESE: Q. And all of these e-mails and correspondence that Mr. Gage showed you was during 2014 and 2015; correct? A. Yes. Q. When you know and everyone at the company knows there are tens of thousands of product liability lawsuits pending against your company for these very products. A. Yes. MR. GAGE: Object to form. BY MR. FREESE: Q. Now, Mr. Gage showed you D-9, this chronology of events? A. Yes. Q. Did any lawyer assist in the preparation of Defense Exhibit No. 9? A. I requested it. I worked with Stacy on it. I don't know if or what kind of input the attorneys had. I just got this after I requested it. Q. You requested this chronology from Ms. Kluesner?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	sources. It was suggested that we put them in there to make it easier for everybody to find the documents. Q. By the lawyers. A. Yes. Q. Now, you remember Mr. Gage asked you questions about your testimony yesterday Dr. Weisberg, do you have your rough transcript from yesterday? A. Is that Q. It's what Mr. Gage showed you. A this one? MR. GAGE: Yeah, that's it. THE WITNESS: I have it. MR. FREESE: Can you identify the exhibit number? I don't have it MR. GAGE: I didn't make it an exhibit number, but MR. FREESE: Okay. That's fair enough. BY MR. FREESE: Q. If you'll turn to page 175, Dr. Weisberg
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	BY MR. FREESE: Q. And all of these e-mails and correspondence that Mr. Gage showed you was during 2014 and 2015; correct? A. Yes. Q. When you know and everyone at the company knows there are tens of thousands of product liability lawsuits pending against your company for these very products. A. Yes. MR. GAGE: Object to form. BY MR. FREESE: Q. Now, Mr. Gage showed you D-9, this chronology of events? A. Yes. Q. Did any lawyer assist in the preparation of Defense Exhibit No. 9? A. I requested it. I worked with Stacy on it. I don't know if or what kind of input the attorneys had. I just got this after I requested it. Q. You requested this chronology from Ms. Kluesner? A. I requested it at a meeting. The	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	sources. It was suggested that we put them in there to make it easier for everybody to find the documents. Q. By the lawyers. A. Yes. Q. Now, you remember Mr. Gage asked you questions about your testimony yesterday Dr. Weisberg, do you have your rough transcript from yesterday? A. Is that Q. It's what Mr. Gage showed you. A this one? MR. GAGE: Yeah, that's it. THE WITNESS: I have it. MR. FREESE: Can you identify the exhibit number? I don't have it MR. GAGE: I didn't make it an exhibit number, but MR. FREESE: Okay. That's fair enough. BY MR. FREESE: Q. If you'll turn to page 175, Dr. Weisberg A. Okay.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	BY MR. FREESE: Q. And all of these e-mails and correspondence that Mr. Gage showed you was during 2014 and 2015; correct? A. Yes. Q. When you know and everyone at the company knows there are tens of thousands of product liability lawsuits pending against your company for these very products. A. Yes. MR. GAGE: Object to form. BY MR. FREESE: Q. Now, Mr. Gage showed you D-9, this chronology of events? A. Yes. Q. Did any lawyer assist in the preparation of Defense Exhibit No. 9? A. I requested it. I worked with Stacy on it. I don't know if or what kind of input the attorneys had. I just got this after I requested it. Q. You requested this chronology from Ms. Kluesner?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	sources. It was suggested that we put them in there to make it easier for everybody to find the documents. Q. By the lawyers. A. Yes. Q. Now, you remember Mr. Gage asked you questions about your testimony yesterday Dr. Weisberg, do you have your rough transcript from yesterday? A. Is that Q. It's what Mr. Gage showed you. A this one? MR. GAGE: Yeah, that's it. THE WITNESS: I have it. MR. FREESE: Can you identify the exhibit number? I don't have it MR. GAGE: I didn't make it an exhibit number, but MR. FREESE: Okay. That's fair enough. BY MR. FREESE: Q. If you'll turn to page 175, Dr. Weisberg

68 (Pages 558 to 561)

1	Page 562		Page 564
1	MR. GAGE: Hang on. Did you say 175?	1	before today.
2	Oh, I'm sorry.	2	MR. GAGE: Object to form.
3	MR. FREESE: This is how it's	3	THE WITNESS: That's not why that
4	paginated. It's down here, 175	4	happened. It happened
5	MR. GAGE: It's down here at the	5	MR. FREESE: Dr. Weisberg, I'm not
6	bottom. It's 190 at the top. It's 175 at the	6	asking you why. I'm saying, you didn't change the
7	bottom.	7	answer to that question until after you took a break
8	I think he's with you.	8	yesterday with your lawyers and came back today and
9	MR. FREESE: The rough pagination is	9	changed it when Mr. Gage asked you the question. Am
10	page 175. Do you see that?	10	I correct?
11	THE WITNESS: Yes.	11	MR. GAGE: Object to form.
12	BY MR. FREESE:	12	MR. FREESE: I'm just asking sequence
13	Q. And then Mr. Gage asked you the	13	of events, sir.
14	question I'm sorry no Mr. Gage just read	14	MR. GAGE: Object to form.
15		15	THE WITNESS: Yes.
16	you this question and answer 30 minutes ago that you	16	BY MR. FREESE:
17	gave yesterday; correct?		1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
	A. Yes.	17	Q. Okay. And the same question on
18	Q. And then he let you explain why the	18	you were asked by I don't want to ask that.
19	answer that you gave yesterday was not a correct	19	Strike that. Now, just a couple more questions, Dr.
20	answer; correct?	20	Weisberg, and I'm going to be done.
21	A. Yes.	21	First of all, you understand that
22	Q. And just so the jury understands in	22	or maybe you don't understand it, but I represent a
23	this case, when you gave that answer, you gave it	23	woman named Jennifer Ramirez in Bear County, Texas.
24	based on your best recollection of events at the	24	Did you know that before today?
25	time; correct?	25	A. I knew that Jennifer Ramirez was one
	Page 563		Page 565
1	A. Yes.	1	of the plaintiffs.
2	Q. And you had three lawyers sitting in	2	Q. You don't know Jennifer Ramirez, do
3	here yesterday, did you not?	3	you?
4	A. Yes.	4	A. No.
5	Q. Before a break was taken, you did not	5	Q. You do not know Cesar Reyes, her
6	change that answer in any way, did you?	6	doctor, do you?
7	A. I don't believe so.	7	A. No.
8	Q. We then took a break and you and the	8	Q. He's the doctor, I'll represent, that
9	three lawyers for Ethicon went out of this room,	9	implanted a TVT-O in Ms. Ramirez. Okay. Did you
10	came back, and after that 30-minute break, attempted	10	know that before today?
11	to amend this answer to this question. Am I	11	MR. GAGE: Object to form.
12	correct?	12	THE WITNESS: I don't know what I
		13	doubt think I be on that I may be one be one it
13	A. That's correct.	1 7 2	don't think I knew that. I may have known it
	A. That's correct. MR. GAGE: Object to form.	14	BY MR. FREESE:
13			BY MR. FREESE:
13 14	MR. GAGE: Object to form. BY MR. FREESE:	14	
13 14 15	MR. GAGE: Object to form. BY MR. FREESE: Q. The same is true with the question	14 15	BY MR. FREESE: Q. You don't know Dr. Reyes. A. No.
13 14 15 16	MR. GAGE: Object to form. BY MR. FREESE: Q. The same is true with the question you were asked about the foreign body reaction, the	14 15 16	BY MR. FREESE: Q. You don't know Dr. Reyes. A. No. Q. You don't know what patient brochure,
13 14 15 16 17	MR. GAGE: Object to form. BY MR. FREESE: Q. The same is true with the question	14 15 16 17	BY MR. FREESE: Q. You don't know Dr. Reyes. A. No.
13 14 15 16 17 18	MR. GAGE: Object to form. BY MR. FREESE: Q. The same is true with the question you were asked about the foreign body reaction, the chronic foreign body reaction do you remember A. Yes.	14 15 16 17 18	BY MR. FREESE: Q. You don't know Dr. Reyes. A. No. Q. You don't know what patient brochure, if any, Dr. Reyes has ever seen; correct? A. That's correct.
13 14 15 16 17 18 19	MR. GAGE: Object to form. BY MR. FREESE: Q. The same is true with the question you were asked about the foreign body reaction, the chronic foreign body reaction do you remember A. Yes. Q you gave that answer multiple	14 15 16 17 18 19	BY MR. FREESE: Q. You don't know Dr. Reyes. A. No. Q. You don't know what patient brochure, if any, Dr. Reyes has ever seen; correct? A. That's correct. Q. And you don't know what version of
13 14 15 16 17 18 19 20 21	MR. GAGE: Object to form. BY MR. FREESE: Q. The same is true with the question you were asked about the foreign body reaction, the chronic foreign body reaction do you remember A. Yes. Q you gave that answer multiple times yesterday, but you only changed it today after	14 15 16 17 18 19 20	BY MR. FREESE: Q. You don't know Dr. Reyes. A. No. Q. You don't know what patient brochure, if any, Dr. Reyes has ever seen; correct? A. That's correct. Q. And you don't know what version of the TVT Obturator IFU Dr. Reyes saw; is that
13 14 15 16 17 18 19 20 21 22	MR. GAGE: Object to form. BY MR. FREESE: Q. The same is true with the question you were asked about the foreign body reaction, the chronic foreign body reaction do you remember A. Yes. Q you gave that answer multiple times yesterday, but you only changed it today after you've had a chance to meet with your lawyers last	14 15 16 17 18 19 20 21 22	BY MR. FREESE: Q. You don't know Dr. Reyes. A. No. Q. You don't know what patient brochure, if any, Dr. Reyes has ever seen; correct? A. That's correct. Q. And you don't know what version of the TVT Obturator IFU Dr. Reyes saw; is that correct?
13 14 15 16 17 18 19 20 21 22 23	MR. GAGE: Object to form. BY MR. FREESE: Q. The same is true with the question you were asked about the foreign body reaction, the chronic foreign body reaction do you remember A. Yes. Q you gave that answer multiple times yesterday, but you only changed it today after you've had a chance to meet with your lawyers last night; correct?	14 15 16 17 18 19 20 21 22 23	BY MR. FREESE: Q. You don't know Dr. Reyes. A. No. Q. You don't know what patient brochure, if any, Dr. Reyes has ever seen; correct? A. That's correct. Q. And you don't know what version of the TVT Obturator IFU Dr. Reyes saw; is that correct? A. That's correct.
13 14 15 16 17 18 19 20 21 22	MR. GAGE: Object to form. BY MR. FREESE: Q. The same is true with the question you were asked about the foreign body reaction, the chronic foreign body reaction do you remember A. Yes. Q you gave that answer multiple times yesterday, but you only changed it today after you've had a chance to meet with your lawyers last	14 15 16 17 18 19 20 21 22	BY MR. FREESE: Q. You don't know Dr. Reyes. A. No. Q. You don't know what patient brochure, if any, Dr. Reyes has ever seen; correct? A. That's correct. Q. And you don't know what version of the TVT Obturator IFU Dr. Reyes saw; is that correct?

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	Page 566		Page 568
1	understood by the least-skilled surgeon who is	1	THE WITNESS: Yes.
2	capable of performing the surgery; is that a fair	2	BY MR. FREESE:
3	statement?	3	Q. Because you assume that every doctor
4	MR. GAGE: Object to form.	4	implanting your company's products has a some
5	THE WITNESS: Yes.	5	baseline adequate amount of training and medical
6	BY MR. FREESE:	6	knowledge in order to perform it; correct?
7	Q. Because you and I understand that	7	A. Yes.
8	there are doctors who perform pelvic surgeries for	8	Q. And you wouldn't waste the doctor's
9	SUI and pelvic organ prolapse that are double	9	time warning them about things that, as you've
10	board-educated urogynecologists, fellowship-trained,	10	described, any pelvic surgeon would know; correct?
11	all the way down to gynecologists who have no	11	MR. GAGE: Object to form.
12	fellowships, who have no board certifications.	12	THE WITNESS: Waste the doctor's time
13	You understand the universe of	13	isn't an expression I would use, but it wouldn't be
14	doctors that implant your product runs from very	14	necessary.
15	sophisticated to less sophisticated, less educated,	15	BY MR. FREESE:
16	less trained physicians; is that a fair statement?	16	Q. Right. And I think you said that
17	MR. GAGE: Object to form.	17	there are certain things that all doctors know.
18	THE WITNESS: Yes.	18	That's why you don't put all the warnings in the
19	BY MR. FREESE:	19	IFU, because there is a there's a presumption at
20 21	Q. And you would agree with me that the	20 21	Johnson & Johnson that there's a baseline of
22	information, the safety information, that's	22	information that all doctors would have, and anyone
23	necessary for a doctor to perform a pelvic organ surgery or a SUI sling surgery, they all need to	23	doing pelvic surgery would know that, so we don't
24	have a minimum amount of ability; correct?	24	have to warn them about it; correct? MR. GAGE: Object to form.
25	A. Yes.	25	THE WITNESS: Yes.
23	Page 567		Page 569
1	Q. Because that's one of the changes you	1	BY MR. FREESE:
2	recommended, right, that the doctor be properly	2	Q. Now, do you have one the IFU in
3	trained; correct?	3	front of you, sir? This may be from yesterday's
4	MR. GAGE: Object to form.	4	1649 is the one I'd like you to look at because this
5	THE WITNESS: I believe that's always	5	is the TVT-O system.
6	been there.	6	A. Would it be down here? 1639, 1649.
7	BY MR. FREESE:	7	Got it.
8	Q. And you've added that patient	8	Q. In the contradictions, it's page 20
9	selection is something that needs to be considered	9	ETH.MESH.27 is the last on the bottom
10	more thoroughly now; correct?	10	right-hand corner? If you'll just go to
11	MR. GAGE: Object to form.	11	contraindications section
12	THE WITNESS: I believe that was	12	A. 2027 is the cover sheet?
13	added somewhere along the line.	13	MR. GAGE: Oh, he's
14	BY MR. FREESE:	14	MR. FREESE: The last two. I'm just
15	Q. The doctor needs to consider the	15	reading the last two of the Bates stamp number.
16	specifics of the patient in deciding whether or not	16	MR. GAGE: That's the one it's on
17	it's an appropriate indicated use for, say, a TVT-O	17	the same page. Look up at the second number.
18	sling; correct?	18	MR. FREESE: 32 then.
19	A. Yes.	19	MR. GAGE: 32? There you go.
20	Q. And I think you told Mr. Gage that	20	THE WITNESS: Okay.
		21	BY MR. FREESE:
21	that the IFU is not intended to warn about all		
22	risks. It's just risks that are that are	22	Q. So 1649, this is the newest, best
22 23	risks. It's just risks that are that are peculiar or unique to your particular product;	22 23	Q. So 1649, this is the newest, best version or most-current version we have of the TVT
22	risks. It's just risks that are that are	22	Q. So 1649, this is the newest, best

70 (Pages 566 to 569)

1 Q. But that's in your IFU. 2 A. Potential. 3 Q potential, including women with 4 plans for future pregnancy. 5 Is that a fact that most surgeons 6 would not know? 7 A. It's a contraindication. I think 1 Q. But that's in your IFU. 2 A. Yes. 3 Q. Acceptable surgical practice should 4 be followed for the procedure, as well as for the 5 management of concomitant is it contaminated 6 infected wounds? 7 A. Yes.	2	Page 570		Page 572
2 Check that real fast. 3 MR. FREESE: Sure. 4 THE WITNESS: Is there a revision 6 5 in the wind? I don't know. Do you have that did somebody take my IFU release page? 6 A. Correct. A. Correct. A. You don't want to operate in an infected area. Q. Do you think most pelvic surgeons would know that you don't want to operate in an infected area. Q. Do you think most pelvic surgeons would know that you don't want to operate in an infected area. Q. Do you think most pelvic surgeons would know that you don't want to operate in an infected area. Q. Do you think most pelvic surgeons would know that you don't want to operate in an infected area. Q. Yet, you put that in the IFU; correct? A. Yes. Q. Yet, you put that in the IFU; correct? A. Yes. Q. Users should be familiar with surgical technique for urethral suspensions and should be adequately trained in Gynecare TV TObturator procedure before employing Gynecare TV Dobturator procedure before employing Gynecare TV Dobturator procedure before employing Gynecare TV Dobturator device, do you see that? Q. Do you think a surgeon needs to be told that he needs to know what he is doing before he does it? A. Yes. Q. Do you think a surgeon needs to be told that he needs to know what he is doing before he does it? A. Yes. A. Yes.	2	THE WITNESS: Revision 5, let me just	1	didn't vou?
MR. FREESE: Sure. THE WITNESS: Is there a revision 6 in the wind? I don't know. Do you have that did somebody take my IFU release page? MR. BARLOW: Just so we don't get crossed up, that is the we marked two copies of the 2015, you know, post-Health Canada. That is not the version that is on the sheet it's the one that we looked at and everybody seemed to agree MS. KABBASH: And I think Adam did the questioning yesterday, and he covered both, so 14 MR. BARLOW: Right. MR. BARLOW: Right. MR. GAGE: So so he's ready to go. We're ready. MS. FREESE: MR. GAGE: So so he's ready to go. We're ready. MS. FREESE: Q. If you'll look in contraindications, it says: As with any suspension surgery, this procedure should not be performed in pregnant papients. Additionally, because Prolene polypropylene will not significantly stretch, it should not be performed in patients with future Page 571 growth A. Potential. Q potential, including women with plans for future pregnancy. Is that a fact that most surgeons would not know? A. It's a contraindication. I think MR. FREESE: Sure. THE WITNESS: Yes. Do you think most pelvic surgeons would know that you don't want to operate in an infected area? A. You don't want to operate in an infected area? A. Yes. Q. Do you think most pelvic surgeons would know that you don't want to operate in an infected area? A. Yes. Q. Yet, you put that in the IFU; correct? A. Yes. Q. Users should be familiar with surgical technique for urethral suspensions and should be adequately trained in Gynecare TV Obturator device, do you see that? A. Yes. Q. Do you think most pelvic surgeons would know that you don't want to operate in an infected area? A. Yes. Q. Outers should be familiar with surgical technique for urethral suspensions and should be adequately trained in Gynecare TV Obturator device, do you see that? A. Yes. Q. Do you think as a urinary tract infection. A. Yes. Q. Do you think nost pelvic surgeons would that he needs to know what he is doing before he does it? A.		•		
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6 somebody take my IFU release page? 7 MR. BARLOW: Just so we don't get 8 crossed up, that is the we marked two copies of 9 the 2015, you know, post-Health Canada. That is not 10 the version that is on the sheet it's the one 11 that we looked at and everybody seemed to agree 12 MS. KABBASH: And I think Adam did 13 the questioning yesterday, and he covered both, so 14 15 MR. BARLOW: Right. 16 MR. GAGE: So so he's ready to go. 17 We're ready. 18 THE WITNESS: Yes. 19 BY MR. FREESE: 19 Q. If you'll look in contraindications, 11 it says: As with any suspension surgery, this 22 procedure should not be performed in pregnant 23 patients. Additionally, because Prolene 24 polypropylene will not significantly stretch, it 25 should not be performed in patients with future Page 571 Page 571 Page 572 Q. Why don't you want to do that? A. You don't want to operate in an infected area. 9 Q. Do you think most pelvic surgeons would know that you don't want to operate in an infected area? A. Yes. Q. Yet, you put that in the IFU; correct? A. Yes. Q. Users should be familiar with surgical technique for urethral suspensions and should be adequately trained in Gynecare TV Obturator procedure before employing Gynecare TV Obturator device, do you see that? A. Yes. Q. Do you think a surgeon needs to be told that he needs to know what he is doing before he does it? A. Yes. Q. Do you think a surgeon needs to be told that he needs to know what he is doing before he does it? A. Yes. Q. But that's in your IFU. A. Yes. Q. Acceptable surgical practice should be followed for the procedure, as well as for the management of concomitant is it contaminated infected wounds? A. Yes. Q. Acceptable surgical practice should be followed for the procedure, as well as for the management of concomitant is it contaminated infected area? A. Yes. Q. But that's in your IFU. A. Yes.				- ·
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4 plans for future pregnancy. 5 Is that a fact that most surgeons 6 would not know? 7 A. It's a contraindication. I think 4 be followed for the procedure, as well as for the 5 management of concomitant is it contaminated 6 infected wounds? 7 A. Yes.	3	Q potential, including women with	3	Q. Acceptable surgical practice should
5 Is that a fact that most surgeons 5 management of concomitant is it contaminated 6 would not know? 6 infected wounds? 7 A. It's a contraindication. I think 7 A. Yes.	4		4	
6 would not know? 6 infected wounds? 7 A. It's a contraindication. I think 7 A. Yes.	5	1 0 0	5	
	6		6	
8 most surgeons would know it. 8 O. Do most pelvic surgeons know that?	7	A. It's a contraindication. I think	7	A. Yes.
ζ. =	8	most surgeons would know it.	8	Q. Do most pelvic surgeons know that?
9 Q. So you think most surgeons would know 9 A. Yes.	9	Q. So you think most surgeons would know	9	
10 that. 10 Q. Do they need to be told that they	10	that.	10	Q. Do they need to be told that they
A. I would think so. 11 need to use acceptable surgical practices?	11	A. I would think so.	11	need to use acceptable surgical practices?
12 Q. Yet, it's in your IFU; correct? 12 A. No.		Q. Yet, it's in your IFU; correct?	12	A. No.
13 A. Yes. 13 Q. Yet, that found its way into your	12	A. Yes.	13	Q. Yet, that found its way into your
Q. Warnings and precautions: Do not use 14 IFU.		Q. Warnings and precautions: Do not use	14	IFU.
15 Gynecare Obturator in patients who are on 15 A. That's right.	13 14	· · · · · · · · · · · · · · · · · · ·		
16 anticoagulation therapy. Do not use Gynecare TVT 16 Q. The procedure should be performed	13 14	anticoagulation therapy. Do not use Gynecare TVT	16	Q. The procedure should be performed
17 Obturator in a patient who has urinary tract 17 with care to avoid large vessels, nerves, bladders,	13 14 15	Obturator in a patient who has urinary tract	17	with care to avoid large vessels, nerves, bladders,
	13 14 15 16		18	and bowel. Attention to patient anatomy and correct
	13 14 15 16 17 18		110	passage of the device will minimize the risk, do you
20 someone on anticoagulation therapy? 20 see that?	13 14 15 16 17 18 19	Why don't you want to use a TVT-O on	129	
21 A. Because they bleed. 21 A. Yes.	13 14 15 16 17 18 19	Why don't you want to use a TVT-O on		see that?
Q. Do you think a pelvic floor surgeon 22 Q. Do you need to tell a pelvic floor	13 14 15 16 17 18 19 20 21	Why don't you want to use a TVT-O on someone on anticoagulation therapy? A. Because they bleed.	20 21	
23 would know that without being told in your IFU? 23 surgeon that	13 14 15 16 17 18 19 20 21	Why don't you want to use a TVT-O on someone on anticoagulation therapy? A. Because they bleed.	20 21	A. Yes.
24 A. I think so. 24 A. No.	13 14 15 16 17 18 19 20 21 22 23	Why don't you want to use a TVT-O on someone on anticoagulation therapy? A. Because they bleed. Q. Do you think a pelvic floor surgeon would know that without being told in your IFU?	20 21 22	A. Yes.Q. Do you need to tell a pelvic floor
Q. Yeah, but you put it in there anyway, 25 Q avoid cutting nerves or other	13 14 15 16 17 18 19 20 21 22 23 24	Why don't you want to use a TVT-O on someone on anticoagulation therapy? A. Because they bleed. Q. Do you think a pelvic floor surgeon would know that without being told in your IFU? A. I think so.	20 21 22 23 24	A. Yes. Q. Do you need to tell a pelvic floor surgeon that A. No.

71 (Pages 570 to 573)

	Page 574		Page 576
1	organs or blood vessels?	1	Some may want to know about vaginal
2	A. No.	2	delivery following this, and what we're basically
3	Q. Okay.	3	telling them is, we don't really know, but at least
4	If you need to tell a surgeon that,	4	we're answering a question that we would frequently
5	he doesn't need to have a scalpel in his hand, does	5	get.
6	he?	6	I think that it's important to know
7	A. You're right.	7	that if there is leg pain for 24 to 48 hours, that
8	Q. Bleeding may occur postoperatively,	8	it is likely to resolve.
9	do you need to tell pelvic surgeons that bleeding	9	They may want to know whether they
10	may be a result in a warning and a precaution from a	10	should prescribe prophylactic antibiotics. We say
11	TVT surgery?	11	it's their choice.
12	A. No.	12	Q. A physician reading this would think
13	Q. Although bladder injury is unlikely	13	that leg pain is not likely going to last more than
14	to occur with this technique, cystoscopy may be	14	24-48 hours, are they?
15	performed at the discretion of the surgeon, does	15	MR. GAGE: Object to the form.
16	every pelvic floor surgeon know that?	16	THE WITNESS: And that's what happens
17	A. Probably.	17	in the majority of cases.
18	Q. But you put it in your IFU anyway.	18	BY MR. FREESE:
19	A. That's right.	19	Q. And in a significant number of cases,
20	Q. Do not remove the plastic sheath	20	women have leg pain beyond 24 or 48 hours with
21	until the tape has been properly positioned, does	21	obturator surgeries, do they not?
22	every pelvic floor surgeon know that?	22	MR. GAGE: Object to form.
23	A. They should know that.	23	THE WITNESS: Not significant
24 25	Q. Okay. But that made it into your IFU, too.	24 25	compared to the number that have been done. BY MR. FREESE:
	Page 575		Page 577
1	A. Yes.	1	Q. So how many women have to have
2	Q. Ensure the tape is placed with no	2	permanent leg pain, Dr. Weisberg, in your opinion,
3	tension under the mid-urethra, does pelvic floor	3	before it becomes a significant amount to Ethicon?
4	surgeons know that, that they don't need to tension	4	MR. GAGE: Object to form.
5	it?	5	THE WITNESS: I don't have an answer
6	A. Well, those who did the pretape	6	for that.
7	slings procedures put them in with tension, so this	7	MR. FREESE: Okay.
8	is something that somebody new to this device may	8	BY MR. FREESE:
9	need to be reminded.	9	Q. This is your newest version of the
10	Q. Okay. So that's the first one that	10	IFU for TVT Obturator, isn't it?
11	actually you think somebody may a pelvic floor	11	A. Yes.
12	surgeon might need to be reminded about.	12	Q. And it's still telling doctors using
13	A. Yes.	13	this TVT-O approach, you should expect a transient
14	Q. Do not perform this procedure if you	14	leg pain of 24 to 48 hours and it will resolve with
15	think the surgical site may be infected or	15	using mild analgesics; correct?
16	contaminated, do you need to tell a surgeon that?	16	MR. GAGE: Object to form.
17	A. No.	17	THE WITNESS: That's what happens
18	Q. Let me ask you this, Dr. Weisberg:	18	most of the time.
19	Is there anything in the warnings and precautions	19	MR. FREESE: That's like Advil.
20	that you think any pelvic floor surgeon wouldn't	20	Right?
21	know?	21	THE WITNESS: Yes.
22	A. Yeah, I think that somebody new to	22	BY MR. FREESE:
23	this might ask if there's any information about	23	Q. Dr. Weisberg, is there a single
24	pregnancy following this procedure. That's in	24	contraindication, a single warning or precaution or
25	there.	25	a single adverse reaction that you think a normal

72 (Pages 574 to 577)

Page 578 Page 580 1 pelvic floor surgeon with just normal, adequate 1 THE WITNESS: This -- most of this 2 training would not know and needs to be informed of 2 stuff is very basic and would fit into that 3 3 least-skilled category. via this IFU? 4 4 BY MR. FREESE: MR. GAGE: Object to form and 5 5 objection, asked and answered. And you've not read Dr. Reyes' 6 6 THE WITNESS: We discussed some that deposition, have you? 7 I thought that they might need to be -- need to know 7 I have not. A. 8 8 or to be reminded. You do not know what he said about O. 9 MR. FREESE: I know. 9 the IFU and what his knowledge was, do you? 10 THE WITNESS: But for the most part, 10 I do not. Α. 11 I think they know most of this. 11 MR. FREESE: Dr. Weisberg, I think BY MR. FREESE: that's all I have. I appreciate your time, sir. 12 12 THE WITNESS: Thank you. 13 O. So for the most part, this is a -- is 13 14 a -- the document itself is meaningless and 14 MR. FREESE: One question. 15 worthless in your mind. 15 BY MR. FREESE: A. Not at all. 16 16 The FDA -- the FDA recommended that 17 MR. GAGE: Objection to form. 17 you not use two adverse reactions sections, did it 18 BY MR. FREESE: 18 not? 19 19 Because it doesn't inform a doctor of A. Correct. 20 20 anything that you believe he doesn't already know or Just out of curiosity, because I'm O. 21 should know; correct? 21 here, you ignored that request of the FDA and didn't 22 MR. GAGE: Object to form. 22 follow the recommendation, because you included two THE WITNESS: If you look at the 23 separate adverse reactions sections in the final 23 first several pages of the document, it explains how IFU: correct? 24 24 25 MR. GAGE: Object to form. 25 to use this device. Page 579 Page 581 1 MR. FREESE: I'm sorry. I apologize. 1 THE WITNESS: My understanding is 2 You didn't understand my question or I asked a bad 2 that we did what they asked and we combined them. 3 3 MR. FREESE: 1649 has two versions -question. 4 THE WITNESS: I think I understood 4 has --5 5 it. THE WITNESS: Well, if we could look 6 BY MR. FREESE: 6 at the redlined version we sent them, we might get a 7 I'm asking you -- no, I asked a bad 7 better idea of how we are going to do this. 8 8 question, I'll admit that. BY MR. FREESE: 9 9 With respect to the precautions, the It's your belief that 1649 is not the O. 10 warnings, and adverse reactions, you believe that's 10 final-final of the TVT-O IFU? all surplusage. It's unnecessary because you 11 MR. GAGE: Object to form. 11 believe all doctors already know or should know THE WITNESS: It may be that -- that 12 12 13 everything contained in those sections; correct? 13 the new one hasn't been printed yet. I don't --MR. GAGE: Object to form and 14 14 BY MR. FREESE: objection, asked and answered. 15 15 But you think they've been combined? Q. 16 THE WITNESS: I believe for the most 16 I believe they have been combined. A. 17 part -- and we spoke about some specifics -- for the 17 MR. FREESE: Thank you. I have no most part, people who understand how to do pelvic further questions. I think Mr. Barlow may have a 18 18 surgery and incontinence surgery already know few questions. Thank you, sir. 19 19 20 everything in this list. 20 (Pause.) 21 BY MR. FREESE: 21 22 22 But we agreed that you've gotta have **EXAMINATION** O. the -- you've gotta be at the level of the 23 23 24 least-skilled capable and adequate surgeon; correct? 24 BY MR. BARLOW: MR. GAGE: Object to form. 25 25 Q. Doctor, Ethicon doesn't know what any

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	Page 582		Page 584
1	given implanting doctor knows or doesn't know about	1	iteration of the IFU?
2	the adverse reactions that can occur with regard to	2	A. I believe it is.
3	its mesh products when they go to perform an implant	3	Q. How is that documented?
4	surgery, do they?	4	A. It will be in the design history
5	MR. GAGE: Object to form.	5	file.
6	THE WITNESS: They don't know	6	Q. It'll be is there a particular
7	specifically what each doctor knows.	7	thing that that's called?
8	BY MR. BARLOW:	8	A. Design it would be under the
9	Q. Exactly.	9	design validation section, the IFU design validation
10	And I believe you testified that	10	section.
11	Ethicon has not performed any scientific study to	11	Q. And how many surgeons are typically
12	determine what pelvic floor surgeons know or don't	12	brought in for this sort of thing?
13	know about the adverse reactions that can occur with	13	A. It depends. There's usually a few
14	their pelvic mesh products, do they have they?	14	sessions, with 10 or 12 in each session.
15	A. That's correct.	15	Q. So we're talking about a few dozen?
16	Q. And Ethicon hasn't performed any	16	A. Yeah.
17	scientific survey with regard to what pelvic floor	17	Q. But there's tens of thousands of
18	surgeons may know or not know about the adverse	18	surgeons that perform these surgeries in the United
19	effects that can happen with regard to their pelvic	19	States; correct?
20	mesh products; correct?	20	A. Well, that's true.
21	MR. GAGE: Object to form.	21	MR. GAGE: Object to form.
22	THE WITNESS: I believe that's	22	BY MR. BARLOW:
23	correct, but I'm not sure.	23	Q. So whatever focus group type thing is
24	BY MR. BARLOW:	24	done with the IFUs, that's not a scientific survey
25	Q. To your knowledge you're not aware	25	or study, is it?
	Page 583		Page 585
1	of any scientific survey of what doctors know or	1	MR. GAGE: Object to form.
2	don't know about the adverse reactions for your	2	THE WITNESS: It's not scientific.
3	pelvic mesh products. Right?	3	BY MR. BARLOW:
4	MR. GAGE: Object to form.	4	Q. Doctor, will you pull out just
5	THE WITNESS: The only the only	5	take a look at 1635, which is the memo to the
6	answer I can give you is that all of our IFUs are	6	project file that purports to be from Lee Hackman?
7	looked at by a panel of people that we bring in to	7	A. I don't know if we ever found it, but
8	look at the IFUs, the panel of doctors, and get	8	go ahead. I know that memo.
9	their opinions on it and ask them whether they	9	Q. Okay. I'm just going to ask you, it
10	this is adequate for them.	10	says: The proposed IFU changes consist of enhancing
11	BY MR. BARLOW:	11 12	the current IFUs to better describe known product
12	Q. And these IFUs are reviewed by are	13	risk or to include hazards not currently identified
13	they key opinion leaders that you all bring in?	14	in the IFUs.
14 15	A. Not necessarily. They're just	15	Do you agree with that? A. That's the task of this this
16	it's a range of people. Q. Are they doctors that are brought in	16	
17		17	particular form that he's that he's working with.
18	that Ethicon feels have significant expertise in the	18	Q. Do you agree that the new IFUs better
19	area of pelvic floor surgery? A. There's a range. There's a range of	19	describe the known product risk? A. Yes.
20	people even sometimes residents, people who are	20	Q. And do you believe that they include
21	new in practice, people who are key opinion leaders.	21	hazards not currently identified in the IFUs?
22	We try to get a range of these people for these	22	A. Well, the hazards that they add are
23		23	not spelled out in the old IFUs; but once again,
23 24	Q. Is that A these sessions.	24	these were things that we assume are common
2 4 25	Q. I'm sorry. Is that done for every	25	knowledge.
<i>)</i> h	V THE SOLLY IS HEAT COME TO EVELY	_ <u>_</u>	KHUWICHYE

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Page 586
                                                                                                         Page 588
1
               Okay. Fair -- setting aside your
                                                           1
                                                                adverse reaction than what is in your IFUs; correct?
2
                                                           2
    assumptions about what doctors may or may not know,
                                                                        MR. GAGE: Object to form.
3
                                                           3
    do the new IFUs include hazards that were not
                                                                        THE WITNESS: Yes.
4
     previously identified in the IFUs?
                                                           4
                                                               BY MR. BARLOW:
5
                                                           5
              Hazards that are spelled out more
                                                                         And, Doctor, the language with regard
                                                           6
                                                               to acute and/or chronic pain, from Exhibit 1640, an
6
     specifically, yes.
7
                                                           7
                                                               IFU that includes that better describes that adverse
               So we're in agreement that the new
8
                                                           8
                                                               risk than what was in your IFUs; correct?
     IFUs better describe product risk; correct?
9
                                                           9
                                                                    A.
                                                                         Yes.
         Α.
10
               Doctor, you would agree with me then
                                                          10
                                                                        MR. GAGE: Object to form.
         Q.
11
     that the language found on -- in Exhibit 1640 with
                                                          11
                                                               BY MR. BARLOW:
    regard to the TVT adverse reactions better describes
12
                                                          12
                                                                         With regard to pain with intercourse,
13
    those adverse reactions than what was found in the
                                                          13
                                                               which may in some patients not resolve, that
14
    IFUs prior to the 2015 revisions; correct?
                                                          14
                                                               language -- an IFU that includes that language would
15
             MR. GAGE: Object to form.
                                                          15
                                                               better describe that adverse reaction than what was
16
             THE WITNESS: Yes.
                                                          16
                                                               in your IFUs; correct?
17
             MR. BARLOW: What's the -- what's the
                                                          17
                                                                    A.
                                                                       Yes.
                                                          18
                                                                        MR. GAGE: Object to form.
18
    objection, Bill?
19
             MR. GAGE: The phrase "better
                                                          19
                                                               BY MR. BARLOW:
    describe" is vague and ambiguous.
                                                          20
20
                                                                          Doctor, with regard to neuromuscular
                                                                    O.
21
             MR. BARLOW: That's fine.
                                                          21
                                                               problems, including acute and/or chronic pain in the
22
             MR. FREESE: Let it go.
                                                          22
                                                               groin, thigh, leg, pelvic and/or abdominal area, an
                                                          23
                                                               IFU for a TVT-O that -- or -- a TVT-O that includes
23
    BY MR. BARLOW:
24
              Doctor, the language regarding
                                                          24
                                                               that language would better describe that adverse
25
    foreign body response with regard to TVT adverse
                                                          25
                                                               reaction than what was in your TVT-O IFUs; correct?
                                                                                                         Page 589
1
     reactions that's found in 1640, an IFU that included
                                                           1
                                                                        MR. GAGE: Object to form.
2
                                                           2
                                                                        THE WITNESS: Yes.
     that language would better describe that adverse
3
     reaction than for the -- with the IFUs without it;
                                                           3
                                                               BY MR. BARLOW:
                                                           4
4
     correct?
                                                                         With regard to neuromuscular
5
                                                           5
             MR. GAGE: Object to form.
                                                                problems, including acute and/or chronic pain in the
6
             THE WITNESS: I'm sorry. I don't
                                                           6
                                                               groin, thigh, leg, pelvic and/or abdominal area, an
7
                                                           7
                                                               IFU for an Abbrevo that included that language would
     understand the question.
                                                           8
8
             MR. BARLOW: Sure.
                                                               better describe that adverse reaction than your
9
                                                           9
     BY MR. BARLOW:
                                                                Abbrevo IFUs; correct?
               With regard to the IFUs that we've
10
                                                          10
                                                                        MR. GAGE: Object to form.
     discussed, excluding -- excluding the IFUs that came
                                                          11
                                                                        THE WITNESS: Yes.
11
12
     out this year, okay, all of my questions going
                                                          12
                                                               BY MR. BARLOW:
13
     forward are going to be about the IFUs prior to the
                                                          13
                                                                         With regard to TVT, original TVT,
                                                               neuromuscular -- an IFU that included the language
14
     Health Canada. Okay?
                                                          14
15
         A.
               Okay.
                                                          15
                                                               neuromuscular problems, including acute and/or
16
         Q.
               Doctor, the language -- well, an IFU
                                                          16
                                                               chronic pain in the groin, pelvic and/or abdominal
     that includes the language regarding foreign body
                                                          17
                                                               area, would better describe -- would better describe
17
     response from Exhibit 1640 better describes that
                                                          18
                                                               that adverse reaction than what was in your TVT
18
19
     adverse reaction than in your IFUs; correct?
                                                          19
                                                               IFUs; correct?
20
             MR. GAGE: Object to form.
                                                          20
                                                                    A.
                                                                         Yes.
21
             THE WITNESS: Correct.
                                                          2.1
                                                                        MR. GAGE: Object to form.
                                                          22
22
     BY MR. BARLOW:
                                                               BY MR. BARLOW:
23
               And the language regarding mesh
                                                          23
                                                                          With regard to the TVT Exact, an IFU
24
     extrusion, exposure, or erosion into the vagina or
                                                          24
                                                               that included the language neuromuscular problems,
     other structures or organs better describes that
                                                          25
25
                                                               including acute and/or chronic pain in the groin,
```

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1 removed in part or whole, significant dissection may 2 be required an IFU that includes that language 3 would better describe that risk than what is what 4 was in your IFUs; correct? 5 A. Yes. 6 MR. GAGE: Object to form. 7 THE WITNESS: Yes. 8 BY MR. BARLOW: 9 Q. And, Doctor, an IFU that included the 10 language that, even with additional surgeries, the 11 adverse reactions may not resolve, would better 12 describe that risk than what was in your previous 13 IFUs; correct? 14 MR. GAGE: Object to form. 15 MR. GAGE: Object to form. 16 Q. An IFU that set forth that de novo urinary obstruction could occur as a result of the use of the sling would better describe that risk than what was in your IFUs; correct? 10 MR. GAGE: Object to form. 11 THE WITNESS: No. I think urinary obstruction is handled. 13 IFUs; correct? 14 MR. GAGE: Object to form. 15 MR. GAGE: Object to form. 16 Q. An IFU that set forth that de novo urinary obstruction could occur as a result of the use of the sling would better describe that risk than what was in your IFUs; correct? 10 MR. GAGE: Object to form. 11 THE WITNESS: No. I think urinary obstruction is handled. 12 Oboctor, an IFU that set forth that 13 User of the WITNESS: No. I think urinary obstruction is handled. 14 Q. Doctor, an IFU that set forth that voiding dysfunction de novo voiding dysfunction	1	Page 590		Page 592
a dverse reaction than what was in your Exact IFUs; d correct? A. Yes. MR. GAGE: Object to form. THE WITNESS: Yes. BY MR. BARLOW: Q. An IFU that includes that these adverse reactions may require surgical treatment would better describe that risk than what was in your previous IFUs; correct? MR. GAGE: Object to form. THE WITNESS: Yes. BY MR. BARLOW: MR. GAGE: Object to form. THE WITNESS: Yes. BY MR. BARLOW: An IFU that included the was in your previous IFUs; correct? MR. GAGE: Object to form. THE WITNESS: Yes. Page 591 MR. GAGE: Object to form. THE WITNESS: Yes. MR. GAGE: Object to form. THE WITNESS: Yes. MR. GAGE: Object to form. THE WITNESS: Yes. MR. GAGE: Object to form. THE WI		pelvic and/or abdominal area would an IFU that	1	A. Yes.
adverse reaction than what was in your Exact IFUs; correct? MR. GAGE: Object to form. THE WITNESS: Yes. BY MR. BARLOW: Q. An IFU that includes that these adverse reactions may not resolve, mould better describe that risk than what was in your previous IFUs; correct? MR. GAGE: Object to form. THE WITNESS: Yes. BY MR. BARLOW: Q. A - an IFU that includes the language, one or more revision surgeries may be encessary to treat these adverse reactions may be required an IFU that included the language, in cases in which Prolene mesh needs to be and yes required an IFU that included the language that, even with additional surgeries, the adverse reactions may not resolve, would better describe that risk than what is what was in your IFUs; correct? A. Yes. BY MR. BARLOW: Correct? MR. GAGE: Object to form. THE WITNESS: Yes. BY MR. BARLOW: Correct? MR. GAGE: Object to form. THE WITNESS: Yes. BY MR. BARLOW: Correct? MR. GAGE: Object to form. THE WITNESS: Yes. BY MR. BARLOW: Correct? MR. GAGE: Object to form. THE WITNESS: Yes. BY MR. BARLOW: Correct? MR. GAGE: Object to form. THE WITNESS: Yes. BY MR. BARLOW: Correct? MR. GAGE: Object to form. THE WITNESS: Yes. Correct? MR. GAGE: Object to form. THE WITNESS: Yes. Correct? MR. GAGE: Object to form. THE WITNESS: Yes. Correct? MR. GAGE: Object to form. THE WITNESS: Yes. Correct? MR. GAGE: Object to form. THE WITNESS: Yes. Correct? MR. GAGE: Object to form. THE WITNESS: Yes. Correct? MR. GAGE: Object to form. THE WITNESS: Yes. Correct? MR. GAGE: Object to form. THE WITNESS: Yes. Correct? MR. GAGE: Object to form. THE WITNESS: Yes. Correct? MR. GAGE: Object to form. THE WITNESS: Yes. Correct? MR. GAGE: Object to form. THE WITNESS: Yes. Correct? MR. GAGE: Object to form. THE WITNESS: Yes. Correct? MR. GAGE: Object to form. THE WITNESS: Yes. Correct? MR. GAGE: Object to form. THE WITNESS: Yes. Correct? MR. GAGE: Object to form. THE WITNESS: Yes. Correct? MR. GAGE: Object to form. THE WITNESS: Yes. Correct? MR. GAGE: Obje				
4 MR. GAGE: Object to form. 7 HE WITNESS: Yes. 8 BY MR. BARLOW: 9 Q. An IFU that includes that these adverse reactions may require surgical treatment would better describe that risk than what was in your previous IFUs; correct? 13 MR. GAGE: Object to form. 14 THE WITNESS: Yes. 15 BY MR. BARLOW: 16 Q. A an IFU that includes the incuses of the sling would better describe that risk than what was in your previous IFUs; correct? 16 In a many result from the sling would better describe that risk than what was in your iff with the sling was used. 17 In the with the sling was used. 18 BY MR. BARLOW: 19 Q. A an IFU that includes the increase of the sling. 19 Detter describe that risk than what was in your previous IFUs; correct? 20 In the with the sling was used. 21 MR. GAGE: Object to form. 22 In the with the sling was used. 23 BY MR. BARLOW: 24 Q. Doctor, an IFU that included the language, in cases in which Prolene mesh needs to be required an IFU that includes that language would better describe that risk than what is what was in your IFUs; correct? 25 A. Yes. 26 MR. GAGE: Object to form. 27 THE WITNESS: Yes. 28 BY MR. BARLOW: 29 Q. Doctor, an IFU that included the language in cases in which Prolene mesh needs to be required an IFU that includes that language would better describe that risk than what was in your IFUs; correct? 3 A. Yes. 3 BY MR. BARLOW: 4 Was in your IFUs; correct? 5 A. Yes. 5 MR. GAGE: Object to form. 6 MR. GAGE: Object to form. 7 THE WITNESS: Yes. 8 BY MR. BARLOW: 9 Q. And, Doctor, an IFU that included the language that, even with additional surgeries, the adverse reactions may not resolve, would better describe that risk than what was in your previous in the surger explication in the describe. Even though it is included in the describe. The that cause frequency. 10 Q. An IFU that included the an included the language will be the describe that risk than what was in your previous in which the sling was used. 18 BY MR. BARLOW: 19 Q. Doctor, an IFU that included the language will b			3	
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23 THE WITNESS: No. 23 BY MR. BARLOW:	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	would better describe that risk than what is what was in your IFUs; correct? A. Yes. MR. GAGE: Object to form. THE WITNESS: Yes. BY MR. BARLOW: Q. And, Doctor, an IFU that included the language that, even with additional surgeries, the adverse reactions may not resolve, would better describe that risk than what was in your previous IFUs; correct? MR. GAGE: Object to form. THE WITNESS: Yes. BY MR. BARLOW: Q. Doctor, an IFU that sets forth that urge de novo urge incontinence may result from the implantation of your devices would better describe that risk than your previous IFUs; correct? A. No.	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	THE WITNESS: Yes. I keep doing that. I'm sorry. MR. GAGE: She's getting it. BY MR. BARLOW: Q. An IFU that set forth that de novo urinary obstruction could occur as a result of the use of the sling would better describe that risk than what was in your IFUs; correct? MR. GAGE: Object to form. THE WITNESS: No. I think urinary obstruction is handled. BY MR. BARLOW: Q. Doctor, an IFU that set forth that voiding dysfunction de novo voiding dysfunction could result from the use of the sling would better describe that risk than what was in your IFUs; correct? MR. GAGE: Object to the form. THE WITNESS: I don't think so. MR. BARLOW: Okay. You disagree on that one.
24 BY MR. BARLOW: 24 Q. With regard to the Gynemesh PS, a IFU	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	would better describe that risk than what is what was in your IFUs; correct? A. Yes. MR. GAGE: Object to form. THE WITNESS: Yes. BY MR. BARLOW: Q. And, Doctor, an IFU that included the language that, even with additional surgeries, the adverse reactions may not resolve, would better describe that risk than what was in your previous IFUs; correct? MR. GAGE: Object to form. THE WITNESS: Yes. BY MR. BARLOW: Q. Doctor, an IFU that sets forth that urge de novo urge incontinence may result from the implantation of your devices would better describe that risk than your previous IFUs; correct? A. No. MR. GAGE: Object to form. THE WITNESS: No.	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	THE WITNESS: Yes. I keep doing that. I'm sorry. MR. GAGE: She's getting it. BY MR. BARLOW: Q. An IFU that set forth that de novo urinary obstruction could occur as a result of the use of the sling would better describe that risk than what was in your IFUs; correct? MR. GAGE: Object to form. THE WITNESS: No. I think urinary obstruction is handled. BY MR. BARLOW: Q. Doctor, an IFU that set forth that voiding dysfunction de novo voiding dysfunction could result from the use of the sling would better describe that risk than what was in your IFUs; correct? MR. GAGE: Object to the form. THE WITNESS: I don't think so. MR. BARLOW: Okay. You disagree on that one. BY MR. BARLOW:
Q. Because of the detrusor language? 25 that included that de novo urinary incontinence	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	would better describe that risk than what is what was in your IFUs; correct? A. Yes. MR. GAGE: Object to form. THE WITNESS: Yes. BY MR. BARLOW: Q. And, Doctor, an IFU that included the language that, even with additional surgeries, the adverse reactions may not resolve, would better describe that risk than what was in your previous IFUs; correct? MR. GAGE: Object to form. THE WITNESS: Yes. BY MR. BARLOW: Q. Doctor, an IFU that sets forth that urge de novo urge incontinence may result from the implantation of your devices would better describe that risk than your previous IFUs; correct? A. No. MR. GAGE: Object to form. THE WITNESS: No. BY MR. BARLOW:	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	THE WITNESS: Yes. I keep doing that. I'm sorry. MR. GAGE: She's getting it. BY MR. BARLOW: Q. An IFU that set forth that de novo urinary obstruction could occur as a result of the use of the sling would better describe that risk than what was in your IFUs; correct? MR. GAGE: Object to form. THE WITNESS: No. I think urinary obstruction is handled. BY MR. BARLOW: Q. Doctor, an IFU that set forth that voiding dysfunction de novo voiding dysfunction could result from the use of the sling would better describe that risk than what was in your IFUs; correct? MR. GAGE: Object to the form. THE WITNESS: I don't think so. MR. BARLOW: Okay. You disagree on that one. BY MR. BARLOW: Q. With regard to the Gynemesh PS, a IFU

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	Page 594		Page 596
1	could result would better describe that risk than	1	formality, so
2	what was in your IFUs; correct?	2	MR. GAGE: I'm sending you all my
3	MR. GAGE: Object to form.	3	hotel bill for tonight and I'm going to send you
4	THE WITNESS: Yes.	4	text messages all night long. I'm going to have
5	BY MR. BARLOW:	5	people come pound on your hotel door
6	Q. An IFU that included that de novo	6	MR. BARLOW: I'm almost done. This
7	urge incontinence could result from the use of the	7	is my last line of questioning.
8	Gynemesh PS would better describe that risk than	8	MR. FREESE: I'm not keeping you from
9	what was in your IFUs; correct?	9	going to get your flight.
10	MR. GAGE: Object to form.	10	MR. BARLOW: Maha can handle this.
11	THE WITNESS: I'm sorry. I need to	11	MR. FREESE: She's chomping at the
12	look at the Gynemesh IFU.	12	bit.
13	MR. BARLOW: Yes, sir. Be my guest.	13	MR. BARLOW: She can say object to
14	THE WITNESS: Do we have one	14	form every bit as good as you, I promise.
15	available?	15	MR. GAGE: Probably better.
16	MR. BARLOW: Yeah, I'm you have	16	THE WITNESS: Unfortunately, I need
17	them in the exhibits. I don't	17	an old one and I'm trying to figure out whether
18	MR. GAGE: Do you know what the	18	MR. GAGE: That's redlined
19	number is?	19	THE WITNESS: Yeah, it's redlined.
20	MR. BARLOW: Not off the top of my	20	It should work. I'm trying to figure out whether
21	head.	21	there's any reference to detrusor instability, and I
22	THE WITNESS: Yeah, I'll give you a	22	don't believe that there is
23	number.	23	MR. GAGE: Oh, I see what you're
24	MR. GAGE: They're in the add file.	24	saying.
25	Is that here?	25	THE WITNESS: because I don't
	Page 595		Page 597
1	MS. KABBASH: If you look at the	1	believe that the Gynemesh should lead to detrusor
2	redline, you can tell. You can tell by the redline	2	instability.
3	Tou can ten by the rednie	3	Okay. I can answer your question.
4	MR. GAGE: So why don't we put that	4	MR. BARLOW: Okay. Now I don't even
5	one at the top.	5	remember what it was. Which one was I on?
6	THE WITNESS: That's the only one I	6	BY MR. BARLOW:
7	need to look at.	7	Q. Doctor, an IFU that included that de
8	MR. GAGE: Okay.	8	novo urge incontinence could result from the use of
9	MS. KABBASH: That's our copy.	9	Gynemesh PS would better describe that risk than
10	MR. GAGE: So I'm going to keep it	10	your IFUs; correct?
11	inside the rubber band so it's still the composite	11	A. Yes, although the risk is low.
12	exhibit	12	Q. I'll tell you what, Doctor, on 1632,
13	MS. KABBASH: That's our copy	13	Exhibit 1632 do you have that in front of you?
14	MR. GAGE: That's our copy.	14	Don't worry about it. It'll be quicker for me to do
15	MS. KABBASH: so it doesn't	15	it this way.
16	matter.	16	An IFU that said that de novo urinary
17	MR. GAGE: Oh, okay. So it doesn't	17	frequency could result from the use of Gynemesh PS
18	matter. I'm going to let him look at our copy.	18	would better describe that risk than what was in
19	MR. BARLOW: Yeah, that's fine.	19	your IFUs; correct?
20	MR. GAGE: So that we don't disturb	20	A. Yes.
21	the pristineness of the original composite, such as	21	MR. GAGE: Object to form.
22	it were.	22	THE WITNESS: I'm sorry.
	11 77 - 10.		
	MR RARIOW. Vou will loom over	22	RY MR RARI OW:
23	MR. BARLOW: You will learn over,	23	BY MR. BARLOW: O And an IFU that said that de novo
	MR. BARLOW: You will learn over, hopefully, the years, hopefully not in this particular litigation, that I don't stand on	23 24 25	BY MR. BARLOW: Q. And an IFU that said that de novo urinary retention could result from the use of

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	Page 598		Page 600
1	Gynemesh PS would better describe that adverse	1	THE WITNESS: that it doesn't
2	reaction better than what was in your IFUs; correct?	2	trigger does not trigger inflammation.
3	MR. GAGE: Object to form.	3	BY MR. BARLOW:
4	THE WITNESS: Yes.	4	Q. Doctor, a Gynemesh PS IFU that
5	BY MR. BARLOW:	5	included mesh extrusion, exposure, and erosion into
6	Q. A IFU that included that de novo	6	the vagina or other structures or organs from the
7	urinary obstruction could result from the use of	7	use of Gynemesh PS would better describe that
8	Gynemesh PS would better describe that risk than	8	adverse reaction than what was in your IFUs;
9	what was in your IFUs; correct?	9	correct?
10	MR. GAGE: Object to form.	10	MR. GAGE: Object to form.
11	THE WITNESS: Yes.	11	THE WITNESS: Better, but very
12	BY MR. BARLOW:	12	unnecessary.
13	Q. An IFU that included an adverse	13	MR. BARLOW: Object to the
14	reaction listing of de novo voiding dysfunction that	14	nonresponsive portion of the answer.
15	could result from the use of Gynemesh PS would	15	BY MR. BARLOW:
16	better describe that risk than what was in your	16	Q. Doctor, a IFU that listed acute
17	IFUs; correct?	17	and/or chronic pain would better describe that risk
18	MR. GAGE: Object to form.	18	than what was in your Gynemesh PS IFUs; correct?
19	THE WITNESS: Yes.	19	A. Yes.
20	BY MR. BARLOW:	20	MR. GAGE: Object to form.
21	Q. A IFU that included the language	21	THE WITNESS: Yes.
22	regarding the foreign body response resulting in	22	BY MR. BARLOW:
23	inflammation, extrusion, erosion, exposure, and	23	Q. Doctor, a IFU that included that
24	fistula formation from the use of Gynemesh PS would	24	pelvic pain, which in some patients may not resolve,
25	better describe that adverse reaction than what was	25	would better describe that adverse reaction than
	Page 599		Page 601
1	in your IFUs; correct?	1	what was in your Gynemesh PS IFUs; correct?
2	MR. GAGE: Object to form.	2	MR. GAGE: Object to form.
3	THE WITNESS: I believe that that was	3	THE WITNESS: Yes.
4	in the original Gynemesh.	4	BY MR. BARLOW:
5	BY MR. BARLOW:	5	Q. An IFU that said that stated that
6	Q. That would have been the language	6	pain with intercourse, which in some patients may
7	that would have had to do with transitory foreign	7	not resolve, would better describe that adverse
8	body response; correct?	8	reaction than what was in your Gynemesh PS IFUs;
9	A. I believe so.	9	correct?
10	Q. Okay.	10	MR. GAGE: Object to form.
11	Then let me amend that to say that	11	THE WITNESS: Yes.
12	one that said that chronic foreign body response	12	BY MR. BARLOW:
13	could result from the use of Gynemesh PS would	13	Q. Doctor, an IFU that included that
14	better describe that risk than what was in your	14	excessive contraction or shrinkage of the tissue
15	IFUs; correct?	15	surrounding the mesh resulting in vaginal scarring,
16	MR. GAGE: Object to form.	16	vaginal tightening, and vaginal shortening would
17	THE WITNESS: Chronic foreign body	17	better describe that risk than what was in your
18	response in itself doesn't lead to those late	18	Gynemesh PS IFUs; correct?
19	complications.	19	MR. GAGE: Object to form.
20	BY MR. BARLOW:	20	THE WITNESS: Yes.
21	Q. Okay. And that's because you believe	21	BY MR. BARLOW:
22	that the chronic foreign body response is not strong	22	Q. An IFU that stated that neuromuscular
23 24	enough; correct?	23 24	problems, including acute and/or chronic pain in the
	A. Well MR. GAGE: Object to form.	25	groin, pelvic and/or abdominal area could result from the Gynemesh PS would better describe that
25	MIR (†A(†H) ()hiert to form	1 / 5	Trom the Cavnemech PX Would better decering that

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	Page 602		Page 604
1	adverse reaction than what was in your IFUs;	1	reactions. There's nothing wrong with them. They
2	correct?	2	weren't inaccurate. When we thought they were, we
3	MR. GAGE: Object to form.	3	didn't add them.
4	THE WITNESS: Yes.	4	And because it was requested and
5	BY MR. BARLOW:	5	because the information is good, we added it. Was
6	Q. An IFU that stated that the adverse	6	it necessary? I don't think so, but they were good.
7	reactions related to the Gynemesh PS may require	7	MR. BARLOW: Object to the
8	surgical treatment would better describe that risk	8	nonresponsive portion of the answer.
9	than what was in your IFUs; correct?	9	BY MR. GAGE:
10	MR. GAGE: Object to form.	10	Q. You were just asked as to whether the
11	THE WITNESS: Yes.	11	changes to the IFU better described various
12	BY MR. BARLOW:	12	potential adverse reactions. Do you recall those
13	Q. An IFU that said, one or more	13	questions?
14	revision surgeries may be necessary to treat the	14	A. Yes.
15	complications resulting from the Gynemesh PS, would	15	Q. How many, if any, of those adverse
16	better describe that potential adverse reaction than	16	reactions were discussed in patient brochures dating
17	what was in your IFUs; correct?	17	back to 2008 and/or 2012?
18	MR. GAGE: Object to form.	18	MR. BARLOW: Object to form.
19	THE WITNESS: Yes.	19	THE WITNESS: Most of them.
20	BY MR. BARLOW:	20	BY MR. GAGE:
21	Q. An IFU that says, in cases in which	21	Q. Did the new IFUs use different
22	the Gynemesh needs to be removed in part or whole,	22	wording than the old IFUs?
23	significant dissection may be required, would better	23 24	A. Yes.
24 25	describe that adverse reaction than what was in your	25	Q. Was that different wording used to
<u> 45</u>	Gynemesh PS IFUs; correct?	_∠5	describe some of these adverse events associated
	Page 603		Page 605
1	MR. GAGE: Object to form.	1	with these devices?
2	MR. GAGE: Object to form. THE WITNESS: Yes.	2	with these devices? MR. BARLOW: Object to form.
2	MR. GAGE: Object to form. THE WITNESS: Yes. BY MR. BARLOW:	2	with these devices? MR. BARLOW: Object to form. THE WITNESS: Yes.
2 3 4	MR. GAGE: Object to form. THE WITNESS: Yes. BY MR. BARLOW: Q. And, Doctor, one that an IFU that	2 3 4	with these devices? MR. BARLOW: Object to form. THE WITNESS: Yes. BY MR. GAGE:
2 3 4 5	MR. GAGE: Object to form. THE WITNESS: Yes. BY MR. BARLOW: Q. And, Doctor, one that an IFU that said that even with revision surgery, or multiple	2 3 4 5	with these devices? MR. BARLOW: Object to form. THE WITNESS: Yes. BY MR. GAGE: Q. Were the IFUs prior to 2015
2 3 4 5 6	MR. GAGE: Object to form. THE WITNESS: Yes. BY MR. BARLOW: Q. And, Doctor, one that an IFU that said that even with revision surgery, or multiple revision surgeries, the adverse reactions or	2 3 4 5 6	with these devices? MR. BARLOW: Object to form. THE WITNESS: Yes. BY MR. GAGE: Q. Were the IFUs prior to 2015 adequate
2 3 4 5 6 7	MR. GAGE: Object to form. THE WITNESS: Yes. BY MR. BARLOW: Q. And, Doctor, one that an IFU that said that even with revision surgery, or multiple revision surgeries, the adverse reactions or complications may not be cured would better describe	2 3 4 5 6 7	with these devices? MR. BARLOW: Object to form. THE WITNESS: Yes. BY MR. GAGE: Q. Were the IFUs prior to 2015 adequate MR. BARLOW: Object to form.
2 3 4 5 6 7 8	MR. GAGE: Object to form. THE WITNESS: Yes. BY MR. BARLOW: Q. And, Doctor, one that an IFU that said that even with revision surgery, or multiple revision surgeries, the adverse reactions or complications may not be cured would better describe that adverse reaction or risk than what was in your	2 3 4 5 6 7 8	with these devices? MR. BARLOW: Object to form. THE WITNESS: Yes. BY MR. GAGE: Q. Were the IFUs prior to 2015 adequate MR. BARLOW: Object to form. BY MR. GAGE:
2 3 4 5 6 7 8 9	MR. GAGE: Object to form. THE WITNESS: Yes. BY MR. BARLOW: Q. And, Doctor, one that an IFU that said that even with revision surgery, or multiple revision surgeries, the adverse reactions or complications may not be cured would better describe that adverse reaction or risk than what was in your Gynemesh PS IFUs; correct?	2 3 4 5 6 7 8 9	with these devices? MR. BARLOW: Object to form. THE WITNESS: Yes. BY MR. GAGE: Q. Were the IFUs prior to 2015 adequate MR. BARLOW: Object to form. BY MR. GAGE: Q or inadequate to describe the
2 3 4 5 6 7 8 9	MR. GAGE: Object to form. THE WITNESS: Yes. BY MR. BARLOW: Q. And, Doctor, one that an IFU that said that even with revision surgery, or multiple revision surgeries, the adverse reactions or complications may not be cured would better describe that adverse reaction or risk than what was in your Gynemesh PS IFUs; correct? MR. GAGE: Object to form.	2 3 4 5 6 7 8 9	with these devices? MR. BARLOW: Object to form. THE WITNESS: Yes. BY MR. GAGE: Q. Were the IFUs prior to 2015 adequate MR. BARLOW: Object to form. BY MR. GAGE: Q or inadequate to describe the adverse reactions associated with those devices?
2 3 4 5 6 7 8 9 10	MR. GAGE: Object to form. THE WITNESS: Yes. BY MR. BARLOW: Q. And, Doctor, one that an IFU that said that even with revision surgery, or multiple revision surgeries, the adverse reactions or complications may not be cured would better describe that adverse reaction or risk than what was in your Gynemesh PS IFUs; correct? MR. GAGE: Object to form. THE WITNESS: Yes.	2 3 4 5 6 7 8 9 10	with these devices? MR. BARLOW: Object to form. THE WITNESS: Yes. BY MR. GAGE: Q. Were the IFUs prior to 2015 adequate MR. BARLOW: Object to form. BY MR. GAGE: Q or inadequate to describe the adverse reactions associated with those devices? MR. BARLOW: Sorry. Object to form.
2 3 4 5 6 7 8 9 10 11	MR. GAGE: Object to form. THE WITNESS: Yes. BY MR. BARLOW: Q. And, Doctor, one that an IFU that said that even with revision surgery, or multiple revision surgeries, the adverse reactions or complications may not be cured would better describe that adverse reaction or risk than what was in your Gynemesh PS IFUs; correct? MR. GAGE: Object to form. THE WITNESS: Yes. MR. BARLOW: Okay. I'm going to pass	2 3 4 5 6 7 8 9 10 11 12	with these devices? MR. BARLOW: Object to form. THE WITNESS: Yes. BY MR. GAGE: Q. Were the IFUs prior to 2015 adequate MR. BARLOW: Object to form. BY MR. GAGE: Q or inadequate to describe the adverse reactions associated with those devices? MR. BARLOW: Sorry. Object to form. THE WITNESS: I believe they were
2 3 4 5 6 7 8 9 10 11 12 13	MR. GAGE: Object to form. THE WITNESS: Yes. BY MR. BARLOW: Q. And, Doctor, one that an IFU that said that even with revision surgery, or multiple revision surgeries, the adverse reactions or complications may not be cured would better describe that adverse reaction or risk than what was in your Gynemesh PS IFUs; correct? MR. GAGE: Object to form. THE WITNESS: Yes.	2 3 4 5 6 7 8 9 10 11 12 13	with these devices? MR. BARLOW: Object to form. THE WITNESS: Yes. BY MR. GAGE: Q. Were the IFUs prior to 2015 adequate MR. BARLOW: Object to form. BY MR. GAGE: Q or inadequate to describe the adverse reactions associated with those devices? MR. BARLOW: Sorry. Object to form. THE WITNESS: I believe they were adequate.
2 3 4 5 6 7 8 9 10 11 12 13 14	MR. GAGE: Object to form. THE WITNESS: Yes. BY MR. BARLOW: Q. And, Doctor, one that an IFU that said that even with revision surgery, or multiple revision surgeries, the adverse reactions or complications may not be cured would better describe that adverse reaction or risk than what was in your Gynemesh PS IFUs; correct? MR. GAGE: Object to form. THE WITNESS: Yes. MR. BARLOW: Okay. I'm going to pass the witness.	2 3 4 5 6 7 8 9 10 11 12 13 14	with these devices? MR. BARLOW: Object to form. THE WITNESS: Yes. BY MR. GAGE: Q. Were the IFUs prior to 2015 adequate MR. BARLOW: Object to form. BY MR. GAGE: Q or inadequate to describe the adverse reactions associated with those devices? MR. BARLOW: Sorry. Object to form. THE WITNESS: I believe they were adequate. MR. GAGE: Nothing further.
2 3 4 5 6 7 8 9 10 11 12 13 14 15	MR. GAGE: Object to form. THE WITNESS: Yes. BY MR. BARLOW: Q. And, Doctor, one that an IFU that said that even with revision surgery, or multiple revision surgeries, the adverse reactions or complications may not be cured would better describe that adverse reaction or risk than what was in your Gynemesh PS IFUs; correct? MR. GAGE: Object to form. THE WITNESS: Yes. MR. BARLOW: Okay. I'm going to pass	2 3 4 5 6 7 8 9 10 11 12 13 14 15	with these devices? MR. BARLOW: Object to form. THE WITNESS: Yes. BY MR. GAGE: Q. Were the IFUs prior to 2015 adequate MR. BARLOW: Object to form. BY MR. GAGE: Q or inadequate to describe the adverse reactions associated with those devices? MR. BARLOW: Sorry. Object to form. THE WITNESS: I believe they were adequate. MR. GAGE: Nothing further. MR. BARLOW: We're off the record.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	MR. GAGE: Object to form. THE WITNESS: Yes. BY MR. BARLOW: Q. And, Doctor, one that an IFU that said that even with revision surgery, or multiple revision surgeries, the adverse reactions or complications may not be cured would better describe that adverse reaction or risk than what was in your Gynemesh PS IFUs; correct? MR. GAGE: Object to form. THE WITNESS: Yes. MR. BARLOW: Okay. I'm going to pass the witness.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	with these devices? MR. BARLOW: Object to form. THE WITNESS: Yes. BY MR. GAGE: Q. Were the IFUs prior to 2015 adequate MR. BARLOW: Object to form. BY MR. GAGE: Q or inadequate to describe the adverse reactions associated with those devices? MR. BARLOW: Sorry. Object to form. THE WITNESS: I believe they were adequate. MR. GAGE: Nothing further. MR. BARLOW: We're off the record. THE VIDEO TECHNICIAN: The time is
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	MR. GAGE: Object to form. THE WITNESS: Yes. BY MR. BARLOW: Q. And, Doctor, one that an IFU that said that even with revision surgery, or multiple revision surgeries, the adverse reactions or complications may not be cured would better describe that adverse reaction or risk than what was in your Gynemesh PS IFUs; correct? MR. GAGE: Object to form. THE WITNESS: Yes. MR. BARLOW: Okay. I'm going to pass the witness. EXAMINATION BY MR. GAGE:	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	with these devices? MR. BARLOW: Object to form. THE WITNESS: Yes. BY MR. GAGE: Q. Were the IFUs prior to 2015 adequate MR. BARLOW: Object to form. BY MR. GAGE: Q or inadequate to describe the adverse reactions associated with those devices? MR. BARLOW: Sorry. Object to form. THE WITNESS: I believe they were adequate. MR. GAGE: Nothing further. MR. BARLOW: We're off the record. THE VIDEO TECHNICIAN: The time is 4:41. We're off the record.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	MR. GAGE: Object to form. THE WITNESS: Yes. BY MR. BARLOW: Q. And, Doctor, one that an IFU that said that even with revision surgery, or multiple revision surgeries, the adverse reactions or complications may not be cured would better describe that adverse reaction or risk than what was in your Gynemesh PS IFUs; correct? MR. GAGE: Object to form. THE WITNESS: Yes. MR. BARLOW: Okay. I'm going to pass the witness. EXAMINATION BY MR. GAGE: Q. Dr. Weisberg, if you thought the	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	with these devices? MR. BARLOW: Object to form. THE WITNESS: Yes. BY MR. GAGE: Q. Were the IFUs prior to 2015 adequate MR. BARLOW: Object to form. BY MR. GAGE: Q or inadequate to describe the adverse reactions associated with those devices? MR. BARLOW: Sorry. Object to form. THE WITNESS: I believe they were adequate. MR. GAGE: Nothing further. MR. BARLOW: We're off the record. THE VIDEO TECHNICIAN: The time is
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	MR. GAGE: Object to form. THE WITNESS: Yes. BY MR. BARLOW: Q. And, Doctor, one that an IFU that said that even with revision surgery, or multiple revision surgeries, the adverse reactions or complications may not be cured would better describe that adverse reaction or risk than what was in your Gynemesh PS IFUs; correct? MR. GAGE: Object to form. THE WITNESS: Yes. MR. BARLOW: Okay. I'm going to pass the witness. EXAMINATION BY MR. GAGE: Q. Dr. Weisberg, if you thought the changes that we've been discussing to the IFUs and	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	with these devices? MR. BARLOW: Object to form. THE WITNESS: Yes. BY MR. GAGE: Q. Were the IFUs prior to 2015 adequate MR. BARLOW: Object to form. BY MR. GAGE: Q or inadequate to describe the adverse reactions associated with those devices? MR. BARLOW: Sorry. Object to form. THE WITNESS: I believe they were adequate. MR. GAGE: Nothing further. MR. BARLOW: We're off the record. THE VIDEO TECHNICIAN: The time is 4:41. We're off the record. (Witness excused.)
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79 (Pages 602 to 605)

	Page 606		Page 608		
1	Weisberg has completed for the day. Maha Kabbash	1	INSTRUCTIONS TO WITNESS		
2	and Alex Barlow have remained to go through and we	2	TISTICOTIONS TO WITH LESS		
3	have gone through all of the exhibits, Plaintiffs'	3	Please read your deposition over		
4	exhibits, from the deposition to determine and	4	carefully and make any necessary corrections. You		
5	identify which ones are subject to the stipulation	5	should state the reason in the appropriate space on		
6	that counsel discussed earlier in the day.	6	the errata sheet for any corrections that are made.		
7	And we're going to read into the	7	After doing so, please sign the		
8	record the exhibit numbers of the exhibits that are	8	errata sheet and date it.		
9	subject to the stipulation: Those exhibits are	9	You are signing same subject to the		
10	P-1608, P-1609, P-1610, P-1611, P-1612, P-1614,	10	changes you have noted on the errata sheet, which		
11	P-1615, P-1616, P-1617, P-1618, P-1619, P-1620,	11	will be attached to your deposition.		
12	P-1621, P-1622, P-1625, P-1626, P-1627, P-1629,	12			
13	P-1630, P-1631, P-1633, P-1634, P-1635, P-1636,	13	original errata sheet to the deposing attorney		
14	P-1639, P-1642 through P-1657, and P-1659 through	14	within thirty (30) days of receipt of the deposition		
15	P-1665, P-1667, P-1668, and P-1669.	15	transcript by you. If you fail to do so, the		
16	And, Alex, do you agree those are the	16	deposition transcript may be deemed to be accurate		
17	documents that are subject to the stipulation?	17	and may be used in court.		
18	MR. BARLOW: I do agree.	18	and may be ased in court.		
19	MS. KABBASH: Okay. We're done on	19			
20	the record. Thank you.)	20			
21	(Deposition concluded at	21			
22	approximately 5:06 p.m.)	22			
23	approximatery 5.00 p.int.)	23			
24		24			
25		25			
	Page 607		Page 609		
1		1	2430 007		
1 2	CERTIFICATE	1	ERRATA		
3	I, KIMBERLY A. CAHILL, a Notary	2	EKKATA		
4	Public and Certified Court Reporter of the State of	3	PAGE LINE CHANGE/REASON		
5	New Jersey, do hereby certify that prior to the	4	THEE ENVE CHARACTERISTIN		
6	commencement of the examination, MARTIN WEISBERG,	5			
7	M.D. was duly sworn by me to testify to the truth,	6			
8	the whole truth and nothing but the truth.	7			
9	I DO FURTHER CERTIFY that the	8			
10	foregoing is a verbatim transcript of the testimony	9			
11	as taken stenographically by and before me at the	10			
12	time, place and on the date hereinbefore set forth,	11			
13 14	to the best of my ability. I DO FURTHER CERTIFY that I am	12			
15	neither a relative nor employee nor attorney nor	13			
16	counsel of any of the parties to this action, and	14			
17		1 5			
18	that I am neither a relative nor employee of such	15			
т О	that I am neither a relative nor employee of such attorney or counsel, and that I am not financially	16			
19		16 17			
19 20	attorney or counsel, and that I am not financially	16 17 18			
19 20 21	attorney or counsel, and that I am not financially	16 17 18 19			
19 20 21 22	attorney or counsel, and that I am not financially interested in the action.	16 17 18 19 20			
19 20 21	attorney or counsel, and that I am not financially interested in the action. KIMBERLY A. CAHILL, CCR, RMR	16 17 18 19 20 21			
19 20 21 22 23	attorney or counsel, and that I am not financially interested in the action. KIMBERLY A. CAHILL, CCR, RMR Notary Number: 2160369	16 17 18 19 20 21			
19 20 21 22	attorney or counsel, and that I am not financially interested in the action. KIMBERLY A. CAHILL, CCR, RMR	16 17 18 19 20 21			

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Confidential - Subject to Stipulation and Order of Confidentiality

	Page 610	
1 2 3	ACKNOWLEDGMENT OF DEPONENT	
4 5 6 7 8 9 10 11 12	I,	
13 14 15 16	MARTIN WEISBERG, M.D. DATE	
18 19 20	Subscribed and sworn to before me this day of, 20 My commission expires:	
21 22 23 24 25	Notary Public	
1 2 3 4 5	Page 611 LAWYER'S NOTES PAGE LINE	
6 7 8 9		
10 11 12 13		
14 15 16 17 18		
19 20 21 22		
23 24 25		

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